

# Exhibit 2

Page 1

1                   IN THE UNITED STATES DISTRICT COURT  
2                   DISTRICT OF NEW JERSEY

3                   MDL NO. 16-2738 (MAS)(RLS)

4           IN RE:   JOHNSON & JOHNSON                 :  
5           TALCUM POWDER PRODUCTS                   :  
6           MARKETING, SALES PRACTICES,               :  
7           AND PRODUCTS LIABILITY                    :  
8           LITIGATION                                   :

9                   Remote deposition of DAVID A.  
10           KESSLER, M.D., taken in the above-entitled  
11           matter before Suzanne J. Stotz, a Certified  
12           Court Reporter (License No. 30XI00184500) and  
13           Notary Public of the State of New Jersey, taken  
14           on Monday, April 8, 2024, commencing at  
15           9:09 a.m. EDT.

<p>Page 2</p> <p>1 A P P E A R A N C E S:</p> <p>2 ATTORNEYS FOR PLAINTIFF:</p> <p>3 (Via videoconference)</p> <p>4 BEASLEY ALLEN LAW FIRM</p> <p>5 BY: LEIGH O'DELL, ESQ., and</p> <p>6 BY: MARGARET M. THOMPSON, ESQ., and</p> <p>7 BY: KELLI ALFRED, ESQ., and</p> <p>8 BY: LEANNA PITTARD, ESQ.</p> <p>9 218 Commerce Street</p> <p>10 Montgomery, Alabama 36104</p> <p>11 (800) 898-2034</p> <p>12 leigh.odell@beasleyallen.com</p> <p>13 - and -</p> <p>14 (Via videoconference)</p> <p>15 ASHCRAFT &amp; GEREL, LLP</p> <p>16 BY: MICHELLE A. PARFITT, ESQ.</p> <p>17 4900 Seminary Road, Suite 650</p> <p>18 Alexandria, Virginia 22311</p> <p>19 (844) 680-0339</p> <p>20 mparfitt@ashcraftlaw.com</p> <p>21 - and -</p> <p>22 (Via videoconference)</p> <p>23 LEVIN PAPANTONIO RAFFERTY, P.A.</p> <p>24 BY: CHRISTOPHER V. TISI, ESQ.</p> <p>25 316 South Baylen Street</p> <p>Pensacola, Florida 32502</p> <p>(850) 435-7000</p> <p>ctisi@levinlaw.com</p> <p>- and -</p> <p>(Via videoconference)</p> <p>GOLOMB LEGAL</p> <p>BY: RICHARD GOLOMB, ESQ.</p> <p>1835 Market Street, Suite 2900</p> <p>Philadelphia, Pennsylvania 19103</p> <p>(215) 278-4449</p> <p>rgolomb@golomblegal.com</p> <p>- and -</p>	<p>Page 4</p> <p>1 I N D E X</p> <p>2</p> <p>3 EXAMINATION Page No.</p> <p>4 DAVID A. KESSLER, M.D.</p> <p>5 BY MR. EWALD 8</p> <p>6</p> <p>7</p> <p>8 E X H I B I T S</p> <p>9</p> <p>10 Exhibit Description Page No.</p> <p>11 Exhibit 1 Curriculum Vitae of David A. Kessler 14</p> <p>12</p> <p>13 Exhibit 2 Amended expert report of David A. Kessler, M.D., dated November 15, 2023 31</p> <p>14</p> <p>15 Exhibit 3 Expert report of David A. Kessler, M.D., dated November 16, 2018 45</p> <p>16</p> <p>17</p> <p>18 Exhibit 4 Invoice, dated December 1, 2018 48</p> <p>19 Exhibit 5 Photograph of materials the witness has 64</p> <p>20</p> <p>21 Exhibit 6 Reliance List Initial Report 82</p> <p>22</p> <p>23 Exhibit 7 First Amended Appendix C Materials Considered 82</p> <p>24</p> <p>25</p>
<p>Page 3</p> <p>1 A P P E A R A N C E S (Continued):</p> <p>2</p> <p>3 ATTORNEYS FOR PLAINTIFF (Continued):</p> <p>4 (Via videoconference)</p> <p>5 WILLIAMS, HART &amp; BOUNDAS, LLP</p> <p>6 BY: BRIAN ABRAMSON, ESQ.</p> <p>7 8441 Gulf Freeway, #600</p> <p>8 Houston, Texas 77017</p> <p>9 (713) 230-2343</p> <p>10 babramson@whlaw.com</p> <p>11 - and -</p> <p>12 (Via videoconference)</p> <p>13 COHEN, PLACITELLA &amp; ROTH, P.C.</p> <p>14 BY: CHRISTOPHER M. PLACITELLA, ESQ., and</p> <p>15 BY: DREW M. RENZI, ESQ.</p> <p>16 2001 Market Street, Suite 2900</p> <p>17 Philadelphia, Pennsylvania 19103</p> <p>18 (215) 567-3500</p> <p>19 cplacitella@cprlaw.com</p> <p>20 drenzi@cprlaw.com</p> <p>21</p> <p>22 ATTORNEYS FOR THE DEFENDANT:</p> <p>23 (Via videoconference)</p> <p>24 KING &amp; SPALDING LLP</p> <p>25 BY: JOHN EWALD, ESQ., and</p> <p>BY: JACK KEESTER, ESQ.</p> <p>1185 Avenue of the Americas, 34th Floor</p> <p>New York, New York 10036</p> <p>(212) 556-2100</p> <p>jewald@kslaw.com</p> <p>jkeester@kslaw.com</p> <p>- and -</p> <p>(Via videoconference)</p> <p>FAEGRE DRINKER BIDDLE &amp; REATH LLP</p> <p>BY: SUSAN M. SHARKO, ESQ.</p> <p>600 Campus Drive</p> <p>Florham Park, New Jersey 07932</p> <p>(973) 549-7000</p> <p>susan.sharko@faegredrinker.com</p>	<p>Page 5</p> <p>1 I N D E X (Continued)</p> <p>2</p> <p>3 E X H I B I T S (Continued)</p> <p>4 Exhibit Name Description Page No.</p> <p>5</p> <p>6 Exhibit 8 First Amended Appendix C Materials Considered 83</p> <p>7</p> <p>8 Exhibit 9 White Paper: IWGACP Scientific Opinions on Testing Methods For Asbestos in Cosmetic Products Containing Talca Bates labeled P-2318 through P-2318_030 141</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13 Exhibit 10 World Health Organization International Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 93, Carbon Black, Titanium Dioxide, and Talc 142</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19 Exhibit 11 Johnson &amp; Johnson Consumer Products, Inc., Authorization for Interim Specification, Bates labeled JNJMX68_000000438 through JNJMX68_000000441 153</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<div>1INDEX (Continued)</div> <div>2</div> <div>3EXHIBITS (Continued)</div> <div>4Exhibit</div> <div>5</div> <div>6Exhibit 16The United States250</div> <div>7Food &amp; Drug</div> <div>8Administration's</div> <div>9response to the 1986</div> <div>10citizen's petition</div> <div>11Exhibit 17Article published in280</div> <div>12"The Microscope" in</div> <div>13Volume 38 Fourth</div> <div>14Quarter 1990</div> <div>15Exhibit 18Johnson &amp; Johnson285</div> <div>16document with the</div> <div>17subject: "Allegation</div> <div>18made by Dutch Consumer</div> <div>19Organization of</div> <div>20Asbestos in our</div> <div>21Overseas Talc -</div> <div>22Project No. 0936.00,"</div> <div>23dated September 20,</div> <div>241973</div> <div>25Exhibit 19Memorandum dated April301</div> <div>2613, 1994, Bates</div> <div>27labeled JNJ 000404835</div> <div>28Exhibit 20Memorandum dated303</div> <div>29July 1, 1994, Bates</div> <div>30labeled JNJ 000016687</div> <div>31and JNJ 000016688</div> <div>32</div> <div>33</div> <div>34</div> <div>35</div> <div>36</div> <div>37</div> <div>38</div> <div>39</div> <div>40</div> <div>41</div> <div>42</div> <div>43</div> <div>44</div> <div>45</div>	<div>Page 7</div>	<div>1I'm happy to -- if you let me look off to the</div> <div>2side or behind me, I'm happy to look around and</div> <div>3give you a general description of this, sir.</div> <div>4Q. Yeah. I don't want to spend too</div> <div>5long with it; but if you can give me a general</div> <div>6overview, that would be great.</div> <div>7A. Got it. I'm not going to go</div> <div>8through the electronics.</div> <div>9Q. Yeah.</div> <div>10A. A couple of monitors. My computer.</div> <div>11I have my report. I have a pad with sheets</div> <div>12attached to it. I'm happy to show you, hold</div> <div>13that up to the camera.</div> <div>14To my right of me, I have probably</div> <div>1525 different large, I would guess, 22 by</div> <div>1617 inch sheets of paper. I don't know maybe</div> <div>17there's 25 different binder clips attached to</div> <div>18those sets of papers. So there's a table set</div> <div>19up with large papers to the side of me.</div> <div>20Behind me, I have maybe -- I don't</div> <div>21know -- 15, 20 binders ranging in size, and I</div> <div>22am happy to walk -- at any time you would like</div> <div>23I will be happy to tell you what's in these</div> <div>24binders. Nothing surprising. Primarily</div> <div>25binders that are -- the documents that are</div>	<div>Page 9</div>

<p style="text-align: right;">Page 10</p> <p>1 cited in my report. There's a binder of epi 2 studies, a binder of lab test studies. There's 3 a binder of FDA documents. But I'm happy to 4 walk through. 5 Is that sufficient? 6 Does that give you a sense. 7 Q. That's -- that's very helpful. And 8 it's, actually, the level I was looking for 9 right now. 10 You mentioned a pad with sheets 11 attached. I wasn't sure what you were 12 referring to when you said that. 13 A. Yeah. So I mean, I have -- there 14 are large sheets of paper, and they're cut and 15 pastes and just things I taped to these large 16 sheets. So there's usually eight -- there may 17 be an 8 1/2 x 11 piece of paper that -- most of 18 these are materials from -- that have been 19 produced. And there's, you know, a page here, 20 a page there; and it's taped on this larger 21 sheet. And I'm happy to hold it up to you if 22 you'd like. 23 Q. All right. What I would suggest is 24 if we can, please, get a copy of that during 25 the break, work with counsel so I can take a</p>	<p style="text-align: right;">Page 12</p> <p>1 BY MR. EWALD: 2 Q. All right. And just as a general 3 matter, I understand you have the sheet in 4 front of you, which is sort of a compilation of 5 a variety of different things, fair? 6 A. Yes, sir, exactly. 7 Q. And are you aware of any materials 8 that are in paper in the room that are not 9 included in either your report or the materials 10 considered list? 11 A. I think generally not. It's 12 possible. Anything's possible, you know. I 13 may have printed off a study, an epi study, or 14 something like that in the last couple of days 15 that ends up here and I've not checked it 16 against the reliance list. The reliance list, 17 as you know, is substantial. 18 Q. It is. 19 A. So I would -- let -- let -- let me 20 not make -- it's certainly possible there's 21 something not on the reliance list. That was 22 not my intent. My intent was to make sure, you 23 know, but some things could have been copied 24 and I printed off and, you know, and you know. 25 Q. And to be clear, it's not a</p>
<p style="text-align: right;">Page 11</p> <p>1 look at what you're -- what you're looking at? 2 A. And I don't want to lawyer, sir, 3 but I'm happy -- there's a lot of materials 4 here -- 5 MS. O'DELL: Let me weigh in on 6 that, John. 7 We're -- we're happy to -- I don't 8 believe there's a facility here to copy it 9 because they're quite large posters. And 10 so we're happy to provide a photo of it so 11 you can see -- 12 MR. EWALD: Sure. 13 MS. O'DELL: -- what's here. After 14 the deposition, we can commission or you 15 can commission Golkow to -- to scan these 16 if you'd like; but -- but I don't 17 believe -- I don't want to assure you we 18 can get a copy because I don't -- 19 MR. EWALD: No. I mean -- no. I 20 appreciate that. And also, I was thinking 21 generally about the size. So a picture 22 with enough resolution where I can look at 23 it during the break would be wonderful. 24 Thank you. 25 MS. O'DELL: Okay.</p>	<p style="text-align: right;">Page 13</p> <p>1 got-you. 2 I want to know as you sit here 3 today, are you aware of any materials that are 4 in the room that you've subscribed that are not 5 contained on your materials considered list. 6 A. I'm happy to go over it through the 7 break and tell you what I printed off during 8 the last couple of days, and then we can check 9 to answer that question specifically. 10 But, you know, I took great pains 11 to make sure that the reliance list was -- 12 with, -- you know, with legal staff; and you 13 have two updated reliance lists to -- you 14 should have. But I'm happy to rethink through 15 what I've printed off and I may have that could 16 potentially not be there. 17 Q. Okay. Thanks. 18 So let's start with the most recent 19 CV that I received from counsel. I'm going to 20 put it on the screen there. Always good first 21 test. 22 Do you see that, Doctor? 23 A. I see -- yes, sir, I see 24 Appendix A. Good job. 25 Q. Well, thank you. That's a good</p>

<p style="text-align: right;">Page 14</p> <p>1 start. Good start.</p> <p>2 So I'll mark this as Exhibit 1.</p> <p>3 (Whereupon, Exhibit 1, Curriculum</p> <p>4 Vitae of David A. Kessler, was marked for</p> <p>5 identification.)</p> <p>6 BY MR. EWALD:</p> <p>7 Q. And this, I will represent, was</p> <p>8 Appendix A to the Amended Report, sir, by</p> <p>9 Dr. Kessler at the end of 2018.</p> <p>10 A. And to make your lift -- I don't</p> <p>11 mean to cut you off, but to make your life</p> <p>12 easier, I just have a copy of my report with</p> <p>13 the appendices in front of me too, sir.</p> <p>14 Q. Okay.</p> <p>15 A. So I'm happy to turn the page, but</p> <p>16 also watch the screen.</p> <p>17 Q. Yes. Whatever is -- whatever is</p> <p>18 easiest for you. So get that in front of you.</p> <p>19 Let me know when you have your CV in front of</p> <p>20 you.</p> <p>21 A. I have -- I'm looking at both sets</p> <p>22 right now. Yes.</p> <p>23 Q. Okay.</p> <p>24 A. The screen and the spiral bound</p> <p>25 report.</p>	<p style="text-align: right;">Page 16</p> <p>1 two things that are -- that I can think of. So</p> <p>2 if you're on page 8 -- there you go, sir. So</p> <p>3 that is -- that's correct, you know. I was on</p> <p>4 the Ellodi board, and I have subsequently, in</p> <p>5 the last month or so, gone back on the Ellodi</p> <p>6 board.</p> <p>7 Q. Okay.</p> <p>8 A. All right. And it says senior</p> <p>9 advisor TPG through 2020. Obviously I went off</p> <p>10 when I went into -- I mean, at 2020. And then</p> <p>11 I've just go back on as a senior advisor.</p> <p>12 I think those things are in effect.</p> <p>13 If not, they're going into effect.</p> <p>14 Q. Okay.</p> <p>15 A. Those -- those are two -- two that</p> <p>16 I'm aware of, sir.</p> <p>17 Q. And so with the caveat that it may</p> <p>18 not fully been in effect, within the last month</p> <p>19 or two, you have rejoined the boards of Ellodi</p> <p>20 Pharmaceuticals and TPG?</p> <p>21 A. One slight modification to your</p> <p>22 statement. I don't mean to quibble.</p> <p>23 Q. Sure.</p> <p>24 A. TPG's not a board. Ellodi is a</p> <p>25 board. TPG I'm just a senior advisor.</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Good. And this was served along</p> <p>2 with your report that was dated November 15th,</p> <p>3 2023.</p> <p>4 Is there a more recent CV of which</p> <p>5 you are aware?</p> <p>6 A. There is not that I'm aware of.</p> <p>7 Q. Are you aware of any revisions that</p> <p>8 should be made to this CV that's dated</p> <p>9 November 15th, 2023?</p> <p>10 A. So no revisions as of that date.</p> <p>11 There may be some other stuff that has happened</p> <p>12 subsequent to that.</p> <p>13 I can think of one thing that may</p> <p>14 have been -- you know, there may be updates,</p> <p>15 you understand, things that happened that are</p> <p>16 not on the CV; but the CV's right. CV's are</p> <p>17 never right. There's always a mistake on the</p> <p>18 CV. You know that.</p> <p>19 Q. What updates are you referring to</p> <p>20 since November 15th, 2023, that you add to the</p> <p>21 CV?</p> <p>22 A. Just for, you know, things like --</p> <p>23 I can think of -- you can see that I was on a</p> <p>24 board in 2020. I think it says in 2020 Ellodi.</p> <p>25 If you go down on page 8, there are</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. All right. An important</p> <p>2 distinction, so I appreciate that.</p> <p>3 Okay. Now, if we go back to the</p> <p>4 first page, my understanding from your report</p> <p>5 is that you left government service most</p> <p>6 recently in January 19th, 2023.</p> <p>7 Does that sound right?</p> <p>8 A. That's exactly correct.</p> <p>9 Q. Okay. So you leave government</p> <p>10 service January 19th, 2023.</p> <p>11 Do you take any well-deserved time</p> <p>12 off?</p> <p>13 A. A complicated answer.</p> <p>14 Q. Okay. How is it complicated?</p> <p>15 A. 600- -- I -- I don't mean to be</p> <p>16 flip. All I mean is, the answer is -- the</p> <p>17 answer is yes, not off; but I'm much more Zen,</p> <p>18 sir.</p> <p>19 I mean --</p> <p>20 Q. Okay.</p> <p>21 A. -- 656 million vaccines and</p> <p>22 antivirals and an intense number of years for</p> <p>23 all of us; is that fair?</p> <p>24 So I think the -- that's behind us.</p> <p>25 But when you use the word "off," I then</p>

<p style="text-align: right;">Page 18</p> <p>1 resumed -- I was on leave, sir. I mean, if I  2 can jump ahead.  3 Q. Sure.  4 A. I was on leave from the University  5 of California, San Francisco; and, you know,  6 they've -- I'm -- I'm back on. I'm back on  7 teaching, et cetera.  8 Q. Okay. And -- and that's really,  9 you know, I'm not trying to get into too much  10 while you were on vacation or anything like  11 that. I really just want to understand.  12 You leave January 19th, 2023.  13 When do you resume activities at  14 University of California?  15 A. Pretty simultaneously. I was on  16 leave, so the leave stopped was I think the way  17 it worked. We can check that.  18 Q. Okay. And so when you resumed  19 shortly after leaving the government in January  20 2023, what were -- what -- what were the  21 contours of your job?  22 A. So I'm -- as it was before, I'm a  23 professor of pediatrics epidemiology and  24 biostat. I teach, and I do my research.  25 Q. Okay. Are you teaching any classes</p>	<p style="text-align: right;">Page 20</p> <p>1 those -- those funds to do that, and I'm  2 working on that.  3 Q. And can you tell me, generally, the  4 nature of the two books that you're currently  5 working on?  6 A. I'm happy to. One is -- I mean,  7 they're consistent with, you know, things I've  8 done.  9 One is on obesity, weight, the  10 public health implications of cardiovascular,  11 metabolic. So I'm working on a research in  12 that area.  13 And I've recently agreed to do a  14 book with a number of historians on the  15 legacy operation -- I mean, putting down the  16 lessons learned from Operation Warp Speed.  17 Q. All right. Apart from your  18 teaching obligations and your research as  19 reflected in part of these upon the two books,  20 any other responsibilities that you currently  21 have at UCSF?  22 A. Just the usual responsibilities,  23 you know. I mean, I get called on to assist in  24 certain, you know, institutional matters to,  25 you know, mentor faculty and just do the --</p>
<p style="text-align: right;">Page 19</p> <p>1 this semester?  2 A. I -- Well, semester's a little hard  3 in the medical world. We go more by -- by  4 years.  5 Yes, I was just teaching last week,  6 for example.  7 Q. And since rejoining UCSF, have you  8 been teaching consistently over that period of  9 time?  10 A. Yeah. I'm a medical  11 school teacher. Yes. I mean, I teach  12 epidemiology and biostat; and I -- you know, I  13 teach sections, et cetera, in the, you know,  14 the principles of epidemiology and biostat and  15 clinical decision-making.  16 And I've -- I've taught that pretty  17 consistently since I've -- I -- I left as I did  18 before I went in.  19 Q. Okay. And in addition to teaching  20 classes, what other responsibilities do you  21 have at UCSF?  22 A. So I -- I am currently -- you know,  23 I am on -- you know, I'm writing two books, to  24 get to the chase. I do my research. I do my  25 writing, you know. I mean, I have, you know,</p>	<p style="text-align: right;">Page 21</p> <p>1 assist colleagues; and those -- those --  2 that's -- those are the primary. Most of my  3 job is research writing, obviously.  4 Q. And I believe that your CV says you  5 have not been an attending pediatrician since  6 2013; is that correct?  7 A. Correct. That's exactly right.  8 Q. All right. So what about on the --  9 well, withdrawn.  10 When you get out of government most  11 recently on January 19th, 2023, we talked about  12 your UCSF.  13 At that point in time, did you also  14 resume working in connection with expert  15 witness work for litigation?  16 A. I've done some, yes.  17 Q. Okay.  18 A. I don't -- I don't think  19 necessarily immediately. I don't want to, you  20 know -- but throughout -- throughout the year  21 I've done some. I'm trying to -- when I say  22 "year," you know, what -- what are we at now?  23 I'm at about 15 months --  24 Q. Right.  25 A. -- 16 months. Yes, I've done some,</p>



<p style="text-align: right;">Page 22</p> <p>1 yes.</p> <p>2 Q. And I'm only looking for the -- the</p> <p>3 cases that, you know, have been disclosed.</p> <p>4 What expert witness work have you</p> <p>5 done since you have come out of government?</p> <p>6 A. So my -- my -- here's my</p> <p>7 recollection. Here's what I have in my head.</p> <p>8 There were two matters that were --</p> <p>9 let's call them legacy matters if that's okay.</p> <p>10 These are matters before I went into</p> <p>11 government; and then, you know, then when I</p> <p>12 came out I got, you know, called again.</p> <p>13 So obviously, this matter, you</p> <p>14 know, that has a longer history going back, I</p> <p>15 think, you know, your first report you're aware</p> <p>16 of.</p> <p>17 There was -- is a matter where I</p> <p>18 testified at trial on a Bard mesh case in</p> <p>19 Columbus, Ohio, last year. That was a legacy</p> <p>20 case that, you know, I -- I believe I had filed</p> <p>21 a report even before I went into government.</p> <p>22 And then there is a lead in baby</p> <p>23 foods case, Hain, Gerber, I don't know what the</p> <p>24 exact status of that consolidation. I don't</p> <p>25 know if there is an MDL that's been formed or</p>	<p style="text-align: right;">Page 24</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Except, for example, clinical work</p> <p>3 in Johnson &amp; Johnson subsidiaries; is that</p> <p>4 something you continue to work on?</p> <p>5 A. I believe that they're -- the</p> <p>6 answer is no -- well, the answer is no. There</p> <p>7 may have been a phone call or two -- I don't</p> <p>8 have a recollection -- from some counsel about</p> <p>9 a question about Pinnacle in the last year, but</p> <p>10 I don't have a firm recollection of that right</p> <p>11 at this moment.</p> <p>12 Q. All right. And we'll get more in</p> <p>13 to it as the deposition proceeds.</p> <p>14 But do you recall approximately</p> <p>15 when you were contacted, after leaving in</p> <p>16 January 2023, by plaintiff's counsel in this</p> <p>17 case about reengaging on this legacy matter?</p> <p>18 A. I apologize, I don't remember the</p> <p>19 month. I'm blocking. You know, if I had to</p> <p>20 guess -- I don't want to guess. I don't recall</p> <p>21 exactly when that phone call came in last year,</p> <p>22 but it obviously came in. You know, my guess</p> <p>23 is it came in -- well, can I speculate, give</p> <p>24 you an approximation?</p> <p>25 Q. Well, I would say I don't need a</p>
<p style="text-align: right;">Page 23</p> <p>1 not. I believe that was -- my recollection</p> <p>2 that's -- that's new since. So it's those</p> <p>3 three -- three matters, one of them including</p> <p>4 this obviously, sir.</p> <p>5 Q. And are there any other, as you</p> <p>6 said, legacy matters of which you are aware</p> <p>7 that you're continuing to work or planning to</p> <p>8 work on since you've come back into government</p> <p>9 service?</p> <p>10 MS. O'DELL: John, you understand</p> <p>11 you're only asking for cases in which</p> <p>12 Mr. Kessler knows --</p> <p>13 MR. EWALD: Yes.</p> <p>14 MS. O'DELL: -- he's been</p> <p>15 disclosed.</p> <p>16 MR. EWALD: Yes.</p> <p>17 THE WITNESS: Known I've been</p> <p>18 disclosed? I'm just trying to think, sir.</p> <p>19 It's possible there's an antitrust</p> <p>20 matter. Let me just not go any further</p> <p>21 than that because I don't know the status</p> <p>22 of disclosure. It may be an antitrust</p> <p>23 matter where I have been contacted.</p> <p>24 Nothing other than that that jumps out at</p> <p>25 me, sir.</p>	<p style="text-align: right;">Page 25</p> <p>1 specific month. I'm generally looking for, you</p> <p>2 know, month, range, or the seasons, whatever is</p> <p>3 the --</p> <p>4 A. Yeah. Again, I could be off on</p> <p>5 this; but my recollection, there was a phone</p> <p>6 call in the spring of last year, right, on</p> <p>7 these matters.</p> <p>8 Q. All right. So I'm not saying it's</p> <p>9 anything close to exactly, but about a year</p> <p>10 ago?</p> <p>11 A. Yeah. I mean, if I could refresh</p> <p>12 my memory -- that's my recollection, yeah.</p> <p>13 Q. And how would you refresh your</p> <p>14 memory?</p> <p>15 A. I would have to -- I would either</p> <p>16 have to check my e-mail to see whether there</p> <p>17 was an e-mail that said, you know, please call</p> <p>18 me or something like that or I can ask.</p> <p>19 Q. Okay. Do you recall the name of</p> <p>20 the plaintiff counsel that reached out to you</p> <p>21 after you left government in January 2023?</p> <p>22 A. I do.</p> <p>23 Q. Who was it?</p> <p>24 A. So I need -- the reason I'm</p> <p>25 hesitating, sir, is it was involving a talc</p>



<p style="text-align: right;">Page 26</p> <p>1 case that was not this case, not the MDL,  2 right.  3 Q. Okay.  4 A. I just want to be careful on  5 whether I've been disclosed in that matter or  6 not. And if I give you the name of that  7 lawyer -- again, I'm happy to check at the  8 break with counsel to make sure I can reveal  9 that. But the phone call that came in was from  10 counsel. It was -- I'm not sure -- I mean, it  11 was a state case. It was not a --  12 Q. Right.  13 A. -- not an MDL case. That's why I'm  14 being a little -- being careful here, sir.  15 Q. Understood. And so we may go back  16 to that if necessary.  17 A. Could you do me a favor?  18 Could you take down, if possible,  19 my CV?  20 I'd love to see you --  21 Q. Okay.  22 A. -- otherwise in thumbnail.  23 Q. I'm happy to do that.  24 A. Thanks.  25 Q. It's good practice anyway.</p>	<p style="text-align: right;">Page 28</p> <p>1 right way to say it.  2 Q. So then you asked that question.  3 What happens next as it relates to  4 your work on this case?  5 A. I get called by either that  6 counsel, unnamed called MDL counsel, or I got  7 called by MDL counsel.  8 Q. Okay. And what was the general  9 message that they communicated?  10 A. I believe at that stage -- again,  11 don't hold me to this, but it was general --  12 the bankruptcy issues are being resolved. It  13 looks like this is moving ahead. Again, I  14 apologize for the timeframe. I'm not --  15 Q. Sure.  16 A. And obviously we would like to --  17 we would like you to continue your work,  18 whatever the word, reengage with the MDL. And  19 I asked -- then I asked State counsel who  20 called me to engage with MDL counsel and make  21 sure these things were -- what's the right  22 word, whatever the right terminology -- not in  23 conflict.  24 Q. All right. I'm assuming, because  25 you're sitting here today, that you got the</p>
<p style="text-align: right;">Page 27</p> <p>1 So we may get back to the identity  2 of the lawyer if it matters; it may not.  3 So I take it, though, in that  4 conversation approximately a year ago, somehow  5 it was communicated to you in that conversation  6 by that unidentified plaintiff's lawyer that  7 the MDL plaintiffs were looking to work with  8 you further?  9 A. Not exactly.  10 Q. Okay. So how does that  11 conversation relate to being reengaged in the  12 MDL?  13 A. I believe I raised the issue that I  14 had done a report in the MDL, and I just -- I  15 wanted to -- I wanted to make sure these things  16 were -- I apologize -- for lack of a better  17 word, synched or whatever. I didn't want to do  18 anything that was conflicted, et cetera.  19 Q. Right.  20 A. So that was how -- so I don't want  21 to use the word I "initiated," but I asked the  22 question then, I mean, if I proceed in this  23 other matter, how does that affect the MDL;  24 where is the MDL. I was not paying attention  25 at all, so I asked a question, I think is the</p>	<p style="text-align: right;">Page 29</p> <p>1 all-clear on the conflict?  2 A. Yeah. I don't think it was -- it  3 wasn't -- there is not -- I don't think there  4 is an official conflict. I don't think there  5 is an official conflict, but I -- I had done  6 the work in the MDL.  7 And I -- while I stopped when I  8 went into government service and I said, hey, I  9 mean, is there -- where are we. They said we  10 want to engage you, engage you again, whatever  11 the right word is. And I said sure. And I  12 just -- I tend not to want to do -- again, I  13 don't want to bind myself exactly, but I don't  14 want to do one work for MDL and one work for  15 the State for the same issues. I want those  16 things to be coordinated.  17 In essence, anything that I say or  18 opinions, they should be good for all, you  19 know, I mean, all coordinated. I just wanted  20 them coordinated. That was what my goal was.  21 Q. So the coordination happens to your  22 satisfaction.  23 And approximately when do you start  24 working in earnest again on this matter?  25 A. It's -- I mean, I've got to work</p>

<p style="text-align: right;">Page 30</p> <p>1 backwards from November. My guess is it is 2 spring that it picks up, that it starts on the 3 MDL. 4 Q. Are you talking, again, like 5 April-May time? 6 A. Yeah. Again, I would have to look 7 at my calendar. It could have been May, June, 8 something like that. But it was certainly of 9 that, my sense it was that order. You know, 10 again, I don't know when the actual bankruptcy, 11 et cetera. So that's why I just -- I 12 apologize. I just don't know. 13 Q. No need to apologize. I 14 understand. 15 So what did you understand -- when 16 you started working again in earnest on this 17 matter after leaving government service in 18 January 2023, what did you understand the scope 19 of your work to be? 20 A. I think probably -- if I can, I'm 21 happy to give it to you -- but I think there's 22 a paragraph I wrote in paragraph 22; is that 23 right? 24 Q. Yes. 25 A. I think that gives you the scope,</p>	<p style="text-align: right;">Page 32</p> <p>1 cosmetic manufacturers and the FDA as well as 2 industry standards," and it goes on to say, "I 3 have been asked to address the duties and 4 conduct of defendant cosmetic companies in the 5 face of a potential health hazard." 6 What defendant cosmetic companies 7 are you opining on in this case? 8 A. I believe that the defending 9 companies are in paragraph 17, sir, of the 10 report. I leave -- I'm aware that a number of 11 them are in bankruptcy. So, you know, I leave 12 it to the lawyers, you know, which ones are at 13 issue and which ones are not. 14 Q. All right. And for purposes of 15 your report and your opinions, do you 16 distinguish between, say, Johnson &amp; Johnson and 17 IMERYS? 18 A. So I have this statement in my 19 report, I believe, somewhere where I say if I 20 referenced the defendant, it applies to the 21 defendants as a whole; but I'm not sure if that 22 is the most helpful to you. 23 Q. Right. 24 A. So there's that general statement. 25 You will see, I mean, in the record that, you</p>
<p style="text-align: right;">Page 31</p> <p>1 sir, you know. There was a scope in the 2 opening report back in, what, 2018, right, in a 3 paragraph, I think, if my memory serves, 4 paragraph 18. But I think -- again, it is 5 the -- to look at the, you know, the 6 responsibilities of the defending cosmetic 7 companies, you know, to -- from a regulatory 8 perspective, based on my experience, and 9 looking at the food and drug statutes, 10 regulations, you know, industry, the guidances, 11 standards, and compliance thereof. 12 Q. All right. 13 MR. EWALD: While we're here on 14 paragraph 22 -- let's go ahead and mark as 15 Exhibit 2 Dr. Kessler's amended expert 16 report in this matter, which is dated 17 November 15, 2023. 18 (Whereupon, Exhibit 2, Amended 19 expert report of David A. Kessler, M.D., 20 dated November 15, 2023, was marked for 21 identification.) 22 BY MR. EWALD: 23 Q. And, Doctor, sticking with 24 paragraph 22, it states, as you referenced, 25 "Focusing on the regulatory interface between</p>	<p style="text-align: right;">Page 33</p> <p>1 know, I had available to me, a discovery record 2 there's obviously documents that are J&amp;J, 3 IMERYS, the old CTFA; so there are different 4 documents. 5 And throughout the report, the 6 report will cite, you know -- I mean, that 7 document probably in the name of, you know, 8 what the institution was that, you know, that 9 that document was from. But I think the -- the 10 major defendant here is J&amp;J. I think we all 11 know that. And I think the others are in 12 bankruptcy, as far as I understand. 13 Q. Well, from a perspective of -- we 14 can get into more detail, but would you agree 15 with me that amongst the documents you reviewed 16 in connection with this litigation, there were 17 some that were internal Luzenac/IMERYS 18 documents? 19 A. There was some documents that were 20 Luzenac/IMERYS documents; is that the question? 21 Q. But that are internal documents, 22 internal memos, internal e-mails that no 23 outside parties that were reflected on a paper 24 document. 25 Do you agree that you reviewed such</p>

<p style="text-align: right;">Page 34</p> <p>1 documents?</p> <p>2 A. I'm not sure of the full scope of</p> <p>3 who saw what documents. I don't want to</p> <p>4 represent whether J&amp;J was cc'd, was a party.</p> <p>5 Sometimes they have multiple parties on those</p> <p>6 documents. We would have to look document by</p> <p>7 document.</p> <p>8 Q. So I guess my question is: Are you</p> <p>9 making any assumptions or your opinions in this</p> <p>10 case that J&amp;J was on notice of any</p> <p>11 IMERYS/Luzenac document?</p> <p>12 MS. O'DELL: Object to the form.</p> <p>13 THE WITNESS: Yeah. I think your</p> <p>14 statement is -- you know, let's take --</p> <p>15 first of all, let me -- my job is not -- I</p> <p>16 don't want to make any assumptions, you</p> <p>17 understand. I mean, the facts are what</p> <p>18 the facts are.</p> <p>19 There are J&amp;J documents. There are</p> <p>20 IMERYS documents. Sometimes those</p> <p>21 documents are the same documents just with</p> <p>22 different Bates numbers, right. I mean,</p> <p>23 I've seen the same document, you know,</p> <p>24 both. It's an IMERYS document and a J&amp;J</p> <p>25 just with different Bates numbers.</p>	<p style="text-align: right;">Page 36</p> <p>1 opinions you're offering in this case?</p> <p>2 A. That's a general statement. I</p> <p>3 don't want to make any blanket statement about</p> <p>4 any assumptions. Let's talk about a specific</p> <p>5 opinion, and we can look. I don't want to make</p> <p>6 a forever statement that there's no assumptions</p> <p>7 on any opinion. And, you know, there's always</p> <p>8 some in some thought process, you know. I</p> <p>9 mean, there are judgments that are made.</p> <p>10 Q. Understood. So is it your</p> <p>11 testimony, though, that, as you sit here today,</p> <p>12 you're not aware of any assumptions that you</p> <p>13 are making with respect to the opinions in this</p> <p>14 case?</p> <p>15 MS. O'DELL: Object to the form.</p> <p>16 THE WITNESS: I would have to think</p> <p>17 about the answer to that question.</p> <p>18 I didn't offer or make any</p> <p>19 assumptions. We all, in any thought</p> <p>20 process, connect dots and make inferences.</p> <p>21 I don't know whether those are assumptions</p> <p>22 or inferences. I would have to -- it's</p> <p>23 just too abstract a statement for me to</p> <p>24 make. But I didn't offer it or make any</p> <p>25 assumptions going in.</p>
<p style="text-align: right;">Page 35</p> <p>1 So I mean, there's no way to sort</p> <p>2 out by a specific document, unless we</p> <p>3 looked at it and really track whose files</p> <p>4 they were in.</p> <p>5 I'm making a general assumption</p> <p>6 that when -- well, "assumption" may be the</p> <p>7 wrong word -- but a general view that J&amp;J</p> <p>8 is a sophisticated, very, you know, expert</p> <p>9 company. And it has general</p> <p>10 responsibilities over its suppliers and,</p> <p>11 you know, its contractors in general, so</p> <p>12 in the manufacture of its product.</p> <p>13 So if -- with regard to the product</p> <p>14 that's Johns- -- we're talking about baby</p> <p>15 powder and the production thereof. I</p> <p>16 guess it's fair to say it filters up to</p> <p>17 J&amp;J. They are the supplier -- if it has</p> <p>18 their suppliers. But I don't want to make</p> <p>19 any specific assumptions.</p> <p>20 BY MR. EWALD:</p> <p>21 Q. Well, we will go back to that in a</p> <p>22 moment.</p> <p>23 But you said that -- am I</p> <p>24 understanding you correctly that you're not</p> <p>25 making any assumptions in connection with</p>	<p style="text-align: right;">Page 37</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Did plaintiff's counsel ask you to</p> <p>3 make any assumptions in connection with your</p> <p>4 opinions in this case?</p> <p>5 A. Absolutely not.</p> <p>6 Q. On the Luzenac/IMERYS document</p> <p>7 issue, I want to give you a hypothetical.</p> <p>8 The hypothetical is that it's, on</p> <p>9 the face of the document, an internal Luzenac</p> <p>10 document, only Luzenac employees are, you know,</p> <p>11 on the to or cc line; no indication on that</p> <p>12 document that it was viewed externally from</p> <p>13 IMERYS/Luzenac.</p> <p>14 Are you with me so far?</p> <p>15 A. I think I understand those two</p> <p>16 parts of your hypothetical.</p> <p>17 Q. If that -- if you look at a</p> <p>18 document like that with no other evidence about</p> <p>19 where the document went or who had knowledge of</p> <p>20 it, are you assuming that J&amp;J is aware of that</p> <p>21 document?</p> <p>22 MS. O'DELL: Object to the form.</p> <p>23 Incomplete hypothetical.</p> <p>24 THE WITNESS: So I hate to give</p> <p>25 this answer. It depends on context.</p>

<p style="text-align: right;">Page 38</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Okay. What's the context?</p> <p>3 A. Well, so is this -- it depends on</p> <p>4 what the other facts are. Is this a -- are we</p> <p>5 talking about -- are there other documents that</p> <p>6 reference the facts in that document?</p> <p>7 Is that a document that stands</p> <p>8 alone on the subject matter that was never</p> <p>9 within the purview of other documents?</p> <p>10 Were there audits done?</p> <p>11 Is this a subject matter that a</p> <p>12 reasonable and responsible company who has its</p> <p>13 supplier working on something would be involved</p> <p>14 in?</p> <p>15 There are a lot of issues that go</p> <p>16 into the answer to that question.</p> <p>17 Q. Let's go back to paragraph 22 in</p> <p>18 your amended report. You state, "I have not</p> <p>19 been asked to opine on causation issues."</p> <p>20 What do you mean by that?</p> <p>21 A. Exactly what I say there. I use</p> <p>22 the word caus- -- well, I used the word</p> <p>23 there -- again, I don't want to play lawyer;</p> <p>24 but in any liability case, I mean, there's --</p> <p>25 there are issues of causation, both general and</p>	<p style="text-align: right;">Page 40</p> <p>1 arise in our discussion or, you know,</p> <p>2 regulatory context, I'm happy to discuss; but I</p> <p>3 don't think my opinions go toward that.</p> <p>4 But there's always -- you know, in</p> <p>5 any regulatory matter, if you look at the FDA,</p> <p>6 statutes may render the, you know, article</p> <p>7 injurious. There's obviously some hazard</p> <p>8 analysis that goes into any regulatory</p> <p>9 analysis. I'm just staying away from causation</p> <p>10 as a legal matter. Again, I'm not wanting to</p> <p>11 play lawyer here.</p> <p>12 Q. I appreciate here.</p> <p>13 So when you say -- how would you</p> <p>14 characterize the hazard analysis that you have</p> <p>15 undertaken with respect to the question of</p> <p>16 whether or not talc exposure can cause ovarian</p> <p>17 cancer?</p> <p>18 A. Well, I have not done any</p> <p>19 independent hazard analysis. I mean, I have</p> <p>20 cited the -- I mean, in this document, what the</p> <p>21 federal agencies and others as a -- you know, I</p> <p>22 mean, as it came up over the years, for</p> <p>23 example, I have cited that asbestos is a</p> <p>24 carcinogen. I have not done an independent</p> <p>25 analysis of that. I have not done an</p>
<p style="text-align: right;">Page 39</p> <p>1 specific.</p> <p>2 Here, as I understand it, it's</p> <p>3 talcum baby powder and ovarian cancer; and the</p> <p>4 issues of general causation, you know, the</p> <p>5 Bradford Hill issues and also in the specific</p> <p>6 plaintiff matter was the plaintiff's cancer</p> <p>7 cause -- or contributed to by the baby powder.</p> <p>8 As far as those matters, while I'm</p> <p>9 a professor of epidemiology, I am happy to</p> <p>10 discuss Bradford Hill, you know, for the</p> <p>11 entire -- you know, as long as you'd like. I'm</p> <p>12 not -- there are other experts that are</p> <p>13 well-qualified that are handling -- that are</p> <p>14 dealing with those issues. And I have not</p> <p>15 studied -- I have not delved into, certainly,</p> <p>16 any specific causation matters. I have not</p> <p>17 looked at any medical records in this matter.</p> <p>18 So I just wanted to upfront put that in.</p> <p>19 Q. Sure. And so am I correct that</p> <p>20 you're not going to be offering any opinions in</p> <p>21 this case about whether exposure to talc can</p> <p>22 cause ovarian cancer?</p> <p>23 A. If those issues go toward causation</p> <p>24 and those elements of the tort, I will not do</p> <p>25 that. If there is something -- if those issues</p>	<p style="text-align: right;">Page 41</p> <p>1 independent hazard analysis of that, but that</p> <p>2 does -- you know, my report does state that, I</p> <p>3 believe.</p> <p>4 Q. So when you talk about -- well,</p> <p>5 before we go to that, you also state, I believe</p> <p>6 it's Footnote 31 -- I mean, it's page 31 --</p> <p>7 Footnote 31 and page 31.</p> <p>8 A. Thanks.</p> <p>9 Q. In your report you say, "As I have</p> <p>10 stated previously" --</p> <p>11 A. Wait a second. Yes.</p> <p>12 Q. The bottom of page 31, Footnote --</p> <p>13 page 31, "As I have stated previously, I am not</p> <p>14 offering any causation opinions regarding the</p> <p>15 health effects of cleavage requirements."</p> <p>16 And that is an accurate statement</p> <p>17 of your position in this matter?</p> <p>18 A. Yeah, I think that's fair.</p> <p>19 Understanding causation is defined as we've</p> <p>20 been discussing it, sure.</p> <p>21 Q. Okay. And you have not undertaken</p> <p>22 any independent hazard analysis of whether or</p> <p>23 not cleavage fragments can cause health</p> <p>24 effects?</p> <p>25 A. I mean, I've looked -- I have</p>



<p style="text-align: right;">Page 42</p> <p>1 reviewed literature on that issue, but I have 2 not done an independent hazard analysis, I 3 mean, as you would testify on a hazard analysis 4 on cleavage fragments. 5 Q. Okay. And you say you reviewed 6 literature on whether or not cleavage fragments 7 can cause health effects. 8 Are you going to be offering any 9 opinions about the health effects that can be 10 caused by exposure to cleavage requirements? 11 A. I don't think in that, as you've 12 stated it, no, I don't intend to do anything 13 with regard to causation of whether cleavage 14 fragments -- I'm not aware of causation -- 15 things that go to causation on cleavage. 16 In the clinical sense, I am aware 17 of certainly, you know, some pre-clinical, you 18 know, in vitro kind of work. I'm happy to talk 19 about cleavage fragments in the regulatory 20 context. 21 Q. All right. There's going to be a 22 fair amount of flipping back and forth. I 23 apologize, Doctor. But if you go back to 24 paragraph 22 in your report. 25 A. I'm happy to do that, sir.</p>	<p style="text-align: right;">Page 44</p> <p>1 exposure to talc? 2 A. I mean, hopefully, we can all agree 3 that asbestos has been determined to be a human 4 carcinogen, that there is -- that that is 5 accepted, that is, exposure to asbestos, 6 asbestiform and other fibrous materials. 7 And the question is: Does talc 8 present those risks. 9 Q. Okay. And so when you're looking 10 at -- well, withdrawn. 11 So you identify -- you have stated 12 that you have not done an independent hazard 13 analysis as it relates to causation issues. 14 Are you relying on the regulatory 15 statements over time for the basis of there 16 being a potential health hazard relating to 17 cosmetic talc exposure? 18 MS. O'DELL: Object to the form. 19 THE WITNESS: I just need to -- if 20 you can pull up the question. Am I 21 relying on the regulatory statements over 22 time for the basis of there being a 23 potential -- I think I'm relying on the 24 scientific literature that the statement 25 by regulatory agencies, the general</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. All right. And so when we have 2 that sentence that follows, "I have been asked 3 to address the duties and conduct of defendant 4 cosmetic companies in the face of a potential 5 health hazard," when you're referring to their 6 duties in that sentence, what duties are you 7 referring to? 8 A. I mean, I think it -- I think I go 9 back to the -- I make reference to the second 10 line -- third line there. It's really the 11 interface between those manufacturers and the 12 FDA and the industry standards that pertain 13 thereto. So it's anything that derives from 14 the Federal Food, Drug, and Cosmetic Act and 15 the guidances, regulations, and industry 16 standards. So it's duties that flow there, 17 sir. 18 Q. Then at the end of that sentence, 19 it talks about "in the face of a potential 20 health hazard." 21 Do you see that? 22 A. Sure. 23 Q. And so my question is: What are 24 you relying on for the proposition that there 25 is a potential health hazard relating to</p>	<p style="text-align: right;">Page 45</p> <p>1 consensus, my 40, 50 years of medical 2 experience, my experience as FDA 3 commissioner, you know, et cetera, that, 4 you know, asbestos is a human carcinogen. 5 Again, I hope we don't have to spend a lot 6 of time on that point. 7 BY MR. EWALD: 8 Q. All right. So I want to go back to 9 your preparation of the first report, and we 10 are going to mark that as Exhibit 3. And that 11 one is dated -- it was really helpful on your 12 amended report that it had the date on the 13 front page. 14 Here we go, Exhibit 3, November 16, 15 2018, first report. 16 (Whereupon, Exhibit 3, Expert 17 report of David A. Kessler, M.D., dated 18 November 16, 2018, was marked for 19 identification.) 20 BY MR. EWALD: 21 Q. Do you have a recollection of 22 approximately when you were retained in 23 connection with that first report in this case? 24 A. If you change that question, take 25 out the word "retained," and when I was first</p>

<p style="text-align: right;">Page 46</p> <p>1 contacted -- and I don't have the definition of</p> <p>2 the word "retained," but I can tell you my</p> <p>3 recollection that it was probably 2016 when I</p> <p>4 was first approached and first conversations.</p> <p>5 I assume I was -- those were</p> <p>6 covered -- you know, there was an attorney work</p> <p>7 product to that. I don't want to use the word</p> <p>8 "retained." You know, I don't think I agreed</p> <p>9 to do a report or anything of that nature, you</p> <p>10 know, instantaneous; but my recollection, it</p> <p>11 was 2016, sir.</p> <p>12 Q. All right. And so when did you</p> <p>13 begin to work in earnest on the work that would</p> <p>14 result in your November 2018 report?</p> <p>15 A. My guess is it was within the prior</p> <p>16 12 months to the submission of the report.</p> <p>17 Q. Okay. So approximately November</p> <p>18 2017 or so is when you began to really work on</p> <p>19 the report?</p> <p>20 A. That's my -- let me just look at</p> <p>21 the signature line here.</p> <p>22 So, again, my guess it was probably</p> <p>23 2018 where most of the work was done. There</p> <p>24 was some -- but there was some initial</p> <p>25 conversations maybe in 2016, in 2017. But my</p>	<p style="text-align: right;">Page 48</p> <p>1 A. Again, these are all my words.</p> <p>2 This is my report. So I dictated it. I</p> <p>3 don't -- I did not type it.</p> <p>4 Q. Okay. Apart from assistance that</p> <p>5 you received from counsel in connection with</p> <p>6 the preparation of your report, did anyone else</p> <p>7 assist in the preparation of either report in</p> <p>8 this matter?</p> <p>9 A. No.</p> <p>10 MR. EWALD: I'm going to mark as</p> <p>11 Exhibit 4 the invoice that we received</p> <p>12 from counsel. So the record is clear,</p> <p>13 it's dated December 1, 2018.</p> <p>14 (Whereupon, Exhibit 4, Invoice,</p> <p>15 dated December 1, 2018, was marked for</p> <p>16 identification.)</p> <p>17 MS. O'DELL: John, could we ask you</p> <p>18 to put that in the chat, please, so</p> <p>19 Dr. Kessler could put it on a larger</p> <p>20 screen?</p> <p>21 MR. EWALD: Sure.</p> <p>22 THE WITNESS: By that means, she</p> <p>23 means -- she's testing my ability to</p> <p>24 navigate the computer screens in front of</p> <p>25 me. Watch, I will disconnect the</p>
<p style="text-align: right;">Page 47</p> <p>1 sense is much of the work was done in 2018, but</p> <p>2 I don't have a firm recollection, sir.</p> <p>3 Q. Did you draft the entire first</p> <p>4 report?</p> <p>5 A. I dictated it, yes.</p> <p>6 Q. Okay. And that applies to the</p> <p>7 whole report?</p> <p>8 A. No. I think that there is a -- I</p> <p>9 think, as mentioned, there are schedules that I</p> <p>10 had assistance done under my guidance. But</p> <p>11 hopefully. The schedules are just objective</p> <p>12 facts that I have directed, put together. But</p> <p>13 certainly, the report -- the report is my</p> <p>14 report.</p> <p>15 Q. What about the materials considered</p> <p>16 list for your first report, who created that?</p> <p>17 A. The materials considered list are</p> <p>18 done certainly with my assistance, but that is</p> <p>19 done with the assistance of counsel. And</p> <p>20 that's true on both reports.</p> <p>21 Q. So just while we're covering it --</p> <p>22 you brought it up -- is it true that, apart</p> <p>23 from the schedules and the materials considered</p> <p>24 list, that you drafted the entirety of your</p> <p>25 amended report in this matter?</p>	<p style="text-align: right;">Page 49</p> <p>1 entire -- can I ask counsel to just come</p> <p>2 and show me where the chat button is?</p> <p>3 I'm good at Zoom. Can I go to Zoom</p> <p>4 here?</p> <p>5 MS. O'DELL: John, I'm going to</p> <p>6 help Dr. Kessler here for a second.</p> <p>7 MR. EWALD: Sure.</p> <p>8 THE WITNESS: Thank you.</p> <p>9 MR. EWALD: Let me know if you have</p> <p>10 any problems dropping it in.</p> <p>11 MR. KEESTER: This is Jake jumping</p> <p>12 in. To drop something into the chat, is</p> <p>13 there a privacy setting I need to undo</p> <p>14 here?</p> <p>15 It's not letting me copy and paste.</p> <p>16 (Discussion held off the record.)</p> <p>17 MR. EWALD: If it's not for this</p> <p>18 document, then it will be for something</p> <p>19 else; so let's just figure it out.</p> <p>20 How about this, we have been going</p> <p>21 almost an hour, a little bit shorter, why</p> <p>22 don't we go off the record.</p> <p>23 THE WITNESS: I'm happy to keep on</p> <p>24 going. Keep on going. I don't want to</p> <p>25 break before -- maybe we will break -- I</p>

<p style="text-align: right;">Page 50</p> <p>1 don't know what time the eclipse is 2 hitting your area, but we can take five 3 minutes there. Let's save it for the 4 eclipse break. 5 MR. EWALD: Jake, are you having 6 any luck? 7 MR. KEESTER: I think I might in a 8 second. Hold on. Let me try this. 9 BY MR. EWALD: 10 Q. While Jake is doing that, I'm going 11 to put it back up; and we'll see what we can 12 accomplish. 13 A. Just scroll down so I can see. 14 Thanks, sir. 15 Q. And so, at least on this one, it's 16 a one-pager. And do you see here -- as I 17 mentioned, the date December 1st, 2018. And it 18 is for a total amount of \$101,364.91. 19 Do you see that, sir? 20 A. I do, sir. 21 Q. And you explained that the total 22 arises from 101 hours at \$1,000 per hour and 23 expenses and then totals up to \$364.91, 24 correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 52</p> <p>1 the first report from my first contact with the 2 parties. It probably was over an extended -- 3 more extended six to seven months. But, again, 4 I don't have a recollection of that, what went 5 into that invoice exactly. 6 Q. All right. And so then -- 7 A. But you can assume that everything 8 that pertained to the -- those -- that MDL or 9 whenever things got wrapped into that MDL, 10 everything was -- everything from the beginning 11 through the time of that invoice got wrapped 12 into that invoice. 13 So you could interpret it as over 14 two years or -- I mean, I don't know. I don't 15 want to misspeak here, but you get the drift. 16 Q. I do. And so how do you keep track 17 of the time spent on this matter before you 18 actually issue the invoice? 19 A. I just tend to write down, scribble 20 on a personal sheet of paper what -- the number 21 of hours that I spent. So it's just a number 22 that is scribbled. 23 Q. All right. And so then you -- who 24 is responsible for issuing invoices? 25 A. I turn it over to counsel, that</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. And fair to say that the invoice 2 that we are looking at here from December 1st, 3 2018, reflects the work through the preparation 4 of your November 2018 report? 5 A. Well said, sir. 6 Q. Have you issued any invoices on 7 work that was conducted after you reengaged in 8 the spring of last year? 9 A. I have not. 10 Q. All right. And do you have a 11 standard practice on when you issue invoices in 12 your expert litigation work? 13 A. My standard practice is not going 14 to be -- maybe a little vague. It is usually 15 when I'm done. But in litigation when you're 16 done is -- you know, has different meanings. 17 You know, whenever there's a segment of work 18 that is done, I tend not -- I do not invoice 19 along the way. I tend to invoice after certain 20 segments of litigation. 21 Q. So, for example, the December 1st, 22 2018, invoice would cover approximately six, 23 seven months of work? 24 A. Probably -- again, let's assume 25 that that was the entirety of the work through</p>	<p style="text-align: right;">Page 53</p> <p>1 counsel being my spouse. 2 Q. And you hand her all the different 3 individual pieces of paper with your scribbles 4 on it? 5 A. Yeah. I hand her the paper. And I 6 tend to -- she -- if you don't mind, just, if 7 you want to keep it up, I'd love to see it. I 8 mean, if you don't mind. 9 Q. Sure. 10 A. Thanks. She tends to ask me to do 11 the math and just give her the total number of 12 hours. 13 Q. Okay. 14 A. And she knows the rate. She will 15 put the invoice together. 16 Q. What is your current rate, Doctor? 17 A. \$1,250. 18 Q. And what would be your estimate on 19 how many hours you spent in connection with the 20 work on this matter after being reengaged in 21 the spring of last year? 22 A. So I think that -- let me just 23 break it up into -- again, I have not added it 24 up specifically. There's no final tabulation. 25 But now that you asked me that question, I</p>



<p style="text-align: right;">Page 54</p> <p>1 looked at it. I think it's fair to say through 2 the report I would say in the mid-500 hours. 3 And it's from November for the last six months. 4 Let's just round it off to about probably 300 5 hours. That would give you a good sense of the 6 number of hours. But, again, I don't have an 7 exact, but it should be in that ballpark. 8 Q. All right. And so understanding 9 it's an estimate, as you sit here today, a 10 reasonable estimate, based on your review, 11 would be 850 hours spent from spring of last 12 year until today? 13 A. It may not be quite that high. 14 Again, yes, as I understand it, you will -- as 15 soon as I do the invoices, you will get the 16 invoices. I leave that to counsel. So you 17 will get it exact. But, yeah, I think -- let's 18 work from 800. It's around that, I think, 19 would be fair. 20 Q. All right. And that is the way it 21 works. But unless you want to come back and 22 see me again, this is my only time to ask you 23 questions. So I'm trying to get an estimate. 24 And I appreciate you having done some work to 25 try to get that estimate.</p>	<p style="text-align: right;">Page 56</p> <p>1 A. Yeah, I think that -- yeah, of 2 course. 3 Q. But just to clarify, in connection 4 with the preparation of your report -- 5 withdrawn. 6 In connection with both reports 7 that you have issued in this matter, did you 8 consult with anybody else other than counsel? 9 A. Not to my knowledge. Nothing that 10 I remember, sir. 11 Q. And just to make sure the question 12 is clear, when I say "consult," I don't want 13 there to be some kind of specific term. 14 Did you communicate with anyone 15 other than counsel in preparation of your two 16 reports in this case about any substantive 17 issue? 18 A. Not that I recall, no. I mean, I 19 did not talk to other experts in this matter. 20 I don't want to say that the word "talc" never 21 arose over the last six years in any other 22 conversation, whatever, not that I recall; but, 23 you know, I mean, this is the work of me, you 24 know, with the record in front of me as a 25 relatively solitary worker -- or solitary</p>
<p style="text-align: right;">Page 55</p> <p>1 A. You sound like my dentist. 2 Q. So the -- if you had to say what 3 went into that approximately 550 hours up to 4 the report November 2023, different buckets, 5 what would you say would be the different 6 buckets? 7 A. What went into -- I'm sorry? What 8 did I do? 9 Q. Yes. Let's say different 10 categories of stuff that you did that went 11 into, ultimately, the preparation of the 12 report? 13 A. I mean, it's research and writing, 14 right. I mean, it's research and writing. 15 It's research, thinking, writing. Obviously, 16 there's conversations I'm dictating. But 17 there's -- I'm doing research. I'm reading. 18 I'm thinking. I'm doing more research. I'm 19 writing. There's conversations, as you know, 20 along the way; and I'm dictating. 21 Q. All right. I'm not interested in 22 the content of the conversations. 23 When you're referring to 24 conversations, are you referring to 25 conversations with counsel?</p>	<p style="text-align: right;">Page 57</p> <p>1 worker. I don't mean to add an adjective in 2 front of me. This is me and my computer 3 screen. 4 Q. Okay. The 300 hours approximately 5 from November until today, if you would break 6 that down into how you spent that 300 hours, 7 what would you say? 8 A. Again, I mean, obviously, there was 9 some -- everything is in preparation for you, 10 right. You know, there's no fine line. I knew 11 we were going to have this opportunity to talk. 12 But there were questions that I was still 13 interested in studying and trying to learn the 14 answers to even after my report was done. So I 15 continued to learn and to study. 16 Q. Okay. And as you sit here today, 17 what were those questions that you continued to 18 learn more about after the issuance of your 19 report November 2023? 20 A. There was one question that just 21 kept on puzzling me. And there was some subset 22 questions that I -- you know, these weren't new 23 questions, but they were questions that I was 24 still trying to learn. 25 And still to this day, sir -- let</p>

<p style="text-align: right;">Page 58</p> <p>1 me just put on the record -- still trying to  2 learn, you know, the full answers. You know, I  3 think my report -- let me just say -- digress  4 for a second and get back to your question.  5 My opinions in the report, the last  6 report, are my opinions. I don't have new  7 opinions. But one always learns more in  8 things, you know, expand upon or give more  9 substance.  10 The question was -- the sort of  11 central question -- that in 1976 J&amp;J, CTFA, I  12 mean, the cosmetic industry, the suppliers,  13 basically said to the agency and to the public  14 we're putting into this existence this  15 laboratory test method, this J4-1, that would  16 assure that talcum powder would be asbestos  17 free.  18 And that statement you can see  19 cited that that date is the agency -- everyone  20 said, okay, good. We now have this quality  21 control method in place in 1976. And then we  22 can, you know, be rest assured there's  23 assurances that the product can be used safely.  24 What puzzled me from -- again, I  25 don't know exactly when the question dawned on</p>	<p style="text-align: right;">Page 60</p> <p>1 question -- that question plagued me for a  2 considerable time, and I wanted to get the  3 answer to that question.  4 Q. And so how did you then -- what I'm  5 wondering, then, is, what additional -- well,  6 withdrawn.  7 Are the additional materials that  8 you reviewed in connection with that puzzling  9 question, as you put it, reflected in your  10 second amended materials considered list?  11 A. Yeah. I mean, again -- I mean, I  12 had access -- the answer is yes, but let me  13 just -- so I had access, and I insisted upon  14 access. One, thank you, meaning the company.  15 You put on the -- in public health something  16 called Facts About Talc, which had thousands of  17 documents of evidence that you saw as relevant.  18 So I had that database. But I had the  19 discovery database.  20 And, you know, there were documents  21 that I had probably seen before doing that  22 report that I went back to, but I continued to  23 search that record to get the answers to that  24 question.  25 And, again, the answers, you</p>
<p style="text-align: right;">Page 59</p> <p>1 me, but it was how could you have a quality  2 system, right, in a J4-1 method and a testing  3 method that assures, okay, we are going to make  4 sure that there's no asbestos that gets in  5 there?  6 How can you never have a positive  7 result after?  8 There was never a quality control  9 rejected sample. And how could that be, right?  10 And then there was sort of -- this  11 sort of adjacent or, you know, associated  12 questions, you know, just in light of the known  13 geology, how could J&amp;J and its suppliers, its  14 contractors, sort of be confident that there  15 was no asbestos in its mined product.  16 I saw that, you know, at various  17 times J&amp;J and its suppliers put in place, you  18 know, a fiber management program, you know,  19 that included, you know, sort of selective  20 mining, et cetera. That program is  21 well-documented in the record.  22 You know, there's a fiber  23 management program. You're managing fibers,  24 but J&amp;J kept on saying there's no asbestos;  25 we've never found asbestos. So that</p>	<p style="text-align: right;">Page 61</p> <p>1 know -- my opinions on the answer to those  2 questions are well laid out, I mean, in the  3 report; but I continued to research it, you  4 know, and to get to the basic -- I mean, as my  5 report says, I think, you know, throughout the  6 manufacturing process J&amp;J, its suppliers, its  7 contractors, the trade association, masked the  8 presence of asbestos in talc throughout that  9 process. And I think my report deals with that  10 in great detail.  11 But that masking -- how that -- how  12 the -- how that got masked and that -- I mean,  13 I think that's the essential, you know --  14 that's my essential takeaway of what the last  15 50 years has been about.  16 Q. And when you say the masking of the  17 presence of asbestos, are you referring to the  18 industry's use of J4-1 method?  19 A. Let me give you what I think went  20 into that, the answer to that question.  21 So I think at first it was the ways  22 that asbestos and the fibers were masked. I  23 think the grinding and crushing and the milling  24 process. If you look at the Raymond roller, if  25 you look at -- if you know about the sieve, you</p>

<p style="text-align: right;">Page 62</p> <p>1 know, what that grinds to. If you know that 2 the product specs for certainly of Grade 25 3 talc, certainly that is the latest talc that 4 I'm aware of, of the raw material, that -- you 5 know, that grinding and processing -- let me 6 expand. 7 So I think it's the grinding and 8 crushing and the milling process down to that 9 micron size of that particle distribution -- I 10 guess the median is, what, 10.9 from -- don't 11 hold me to it -- with a range of 7 to 14. Once 12 you grind it and you crush to that, the fact 13 the sample needs to be passed through this 14 minus 325 mesh prior to testing at further 15 impacts, you know, particle dimensions, the 16 extremely low sensitivity. 17 If you look at the how it was 18 validated of the test leading to a false 19 negative, the numerous requirements that had to 20 be met to report a positive finding, the 21 practice of retesting a positive result that 22 sort of -- the head scratcher, that J4-1 was 23 never set out. There was no adequate method to 24 detect chrysotile from the beginning. 25 The fact that improved sensitivity</p>	<p style="text-align: right;">Page 64</p> <p>1 materials that Dr. Kessler has in front of 2 him, send them to my e-mail address or to 3 Suzanne, and she can forward them along, 4 that would be great. 5 MS. O'DELL: John, I will be happy 6 to do that. 7 We will take five minutes. 8 MR. EWALD: That's fine for me. 9 (Whereupon, a break was taken.) 10 BY MR. EWALD: 11 Q. All right. Doctor, a couple of 12 things I wanted to clear up, and then we'll go 13 in a different direction. 14 First, let's mark as Exhibit 5 a 15 picture that counsel provided over the break 16 that reflects the materials that you have -- 17 some of the materials you have. 18 Are the materials in front of you 19 or behind you? 20 A. I have materials in front of me, to 21 the side of me, and behind me. 22 (Whereupon, Exhibit 5, Photograph 23 of materials the witness has, was marked 24 for identification.) 25</p>
<p style="text-align: right;">Page 63</p> <p>1 methods were never utilized. The fact that 2 testing was not reliable and companies knew 3 about it from laboratory to laboratory. The 4 fact that other methods were known to be more 5 sensitive, but were not used for many years. I 6 mean, you put all the totality together, you 7 know. 8 Back in 1973 you look at the 9 Federal Register. FDA says or the government 10 says it recognizes that asbestos -- it's 11 reasonable to expect asbestos is going to be in 12 talc. And put in method J4-1, and it's always 13 no asbestos is ever found, right. Asbestos has 14 always been there. It's just been masked in my 15 opinion. 16 Q. Okay. Thank you. 17 And how about this -- it's not as 18 much for you, Dr. Kessler, as much for Suzanne, 19 the court reporter, to get a short break. 20 And how about this: Let's go off 21 the record. And I saw you a couple of times 22 looking down, which is totally fine, at what 23 was in front of you. 24 MR. EWALD: So, Leigh, if during 25 the break you can take pictures of the</p>	<p style="text-align: right;">Page 65</p> <p>1 BY MR. EWALD: 2 Q. Understood. But the large paper 3 sheets with papers on them, is that actually in 4 front of you right now? 5 A. I have papers in front of me and to 6 the side of me. I don't think any are behind 7 me. I have them to the front of me and to the 8 side of me is my understanding. 9 Q. And so at least from the picture, 10 it appears that these are things, like your 11 report, there's a clamped set of documents with 12 an orange label on the front saying, 13 "Processing Windsor Mill," right? 14 A. That's the -- again, I apologize. 15 I have not seen the pictures. Counsel took the 16 pictures. It's not shared with me. But, 17 processing, yes, that's to the side of me. 18 There are pictures of -- those are folders to 19 the side of me, yes, sir. 20 Q. Okay. And so I don't want to get 21 too bogged down on this. 22 But the clipped sets of documents 23 with orange titles on the front, those are 24 located to your right? 25 A. That's correct.</p>

<p style="text-align: right;">Page 66</p> <p>1 I'm going ask to counsel just a 2 quick question. 3 MS. O'DELL: John, one thing would 4 be helpful is if you're describing it, if 5 you put up the picture so he sees what 6 you're seeing, because I did not show 7 those to Dr. Kessler. 8 MR. EWALD: Sure. 9 MS. O'DELL: John, if you want 10 someone to have a more detailed look at 11 these, you're welcome to send someone 12 over. Obviously, Johnson &amp; Johnson is 13 quite close; and they can look at these 14 materials. 15 MR. EWALD: I appreciate that. And 16 I do think that after the deposition, I 17 would ask on the record that they be kept 18 where they are in the deposition. And we 19 will have somebody either copy them or 20 take a look at them. 21 BY MR. EWALD: 22 Q. But right now what I'm just trying 23 to figure out is what, if anything, do you have 24 in front of you right now, Dr. Kessler? 25 A. So I have a pad that has about --</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. EWALD: I understand. I guess 2 I only received -- maybe we can do this 3 off the record. 4 THE COURT REPORTER: Would you like 5 to go off the record? 6 MS. O'DELL: No. 7 MR. EWALD: Okay. I got one 8 picture. Over the break we'll figure this 9 out. 10 BY MR. EWALD: 11 Q. Anyway, the orange piles with -- 12 A. Yes, sir. 13 Q. -- or the piles with the orange 14 label in front, who put those documents 15 together? 16 A. They were done with me, and I had 17 two -- I apologize for the term -- two task 18 rabbits that sometimes come to the house and 19 helped me paste papers on paper over the 20 weekend. 21 Q. Okay. On the preparation for 22 today's deposition, how many times did you meet 23 with counsel to prepare for today's deposition? 24 A. I don't mean to be -- you know, I 25 don't mean to parse your question. I mean,</p>
<p style="text-align: right;">Page 67</p> <p>1 don't hold it to me -- maybe it's 20 pages, 2 okay. It's clipped with one clip, and there ' 3 a page in front of me that says, "Folders." 4 And all those orange things that 5 are to the right of me have a name, and that 6 list of all those folders are there. So -- and 7 then I have -- on the pad in front of me, I 8 have about 10, 15 pages of paper that have 9 various documents that are pasted on those 10 pieces of paper. 11 And the first page is -- that goes 12 to the -- what I think is the essential -- you 13 asked me about the question about what I have 14 been researching and studying, the ways 15 asbestos in fibers were masked in front of me. 16 MR. EWALD: So we would request 17 over the next break pictures of the 18 15 pages that are actually in front of 19 Dr. Kessler. The question -- 20 MS. O'DELL: I would say, John, we 21 provided a picture of that. So I sent 22 three pictures, and I gave you a picture 23 of, not every page, but certainly what is 24 in front of him. And so just trying to 25 short circuit this.</p>	<p style="text-align: right;">Page 69</p> <p>1 I've been preparing for the deposition for a 2 long time. So I think what you mean, 3 Ms. O'Dell came to the house yesterday, I think 4 a little on Saturday; and Sunday Dr. Thompson 5 similarly arrived this weekend. But, you know, 6 obviously, preparations over -- everything is 7 preparation. 8 Q. Okay. And did you meet with any 9 lawyers in preparation for today's deposition 10 last week? 11 A. I'm sure there were calls on -- I'm 12 sure there were telephone calls last week. 13 Yes, I'm sure. 14 Q. But were there -- there were not 15 any in-person meetings with counsel in 16 preparation for today's deposition last week? 17 A. No. Everything was -- my 18 recollection was Saturday and Sunday. 19 Q. All right. So before being 20 retained as an expert in this case, what did 21 you know about asbestos? 22 A. I certainly knew about the asbestos 23 as a cause of mesothelioma. 24 Q. Okay. What else? 25 A. I certainly -- you know, I had</p>

<p style="text-align: right;">Page 70</p> <p>1 gone -- I had come out of a generation of -- I</p> <p>2 mean, my work -- my early work was in</p> <p>3 laboratories of cancer research. So I was</p> <p>4 certainly -- I mean, always certainly general</p> <p>5 aware of the theories of carcinogenicity.</p> <p>6 Q. Did any of your lab research relate</p> <p>7 to asbestos?</p> <p>8 A. Not the -- no. I mean, it was only</p> <p>9 carcinogenicity and the mechanisms of</p> <p>10 carcinogenicity. And certainly, you know, I</p> <p>11 was involved in tobacco carcinogenicity.</p> <p>12 Q. Before you were retained as an</p> <p>13 expert in this case, did you ever hear the word</p> <p>14 "asbestiform"?</p> <p>15 A. I'm sure I've heard the word</p> <p>16 "asbestiform." I don't have a specific</p> <p>17 recollection, but I'm sure I've heard the word</p> <p>18 "asbestiform."</p> <p>19 Q. Did you have an understanding --</p> <p>20 A. It --</p> <p>21 Q. Go ahead.</p> <p>22 A. I apologize. I stepped on you.</p> <p>23 Q. Did you have an understanding --</p> <p>24 that wasn't the best question by me.</p> <p>25 Did you have an understanding,</p>	<p style="text-align: right;">Page 72</p> <p>1 in this case, were you aware that there were</p> <p>2 different types of asbestos?</p> <p>3 A. Again, I don't have an exact sense</p> <p>4 of -- you know, I do -- there were different</p> <p>5 minerals, et cetera, that were -- that could --</p> <p>6 they were classified in fiber form. And as</p> <p>7 asbestos, I don't remember exactly what I knew</p> <p>8 before or afterwards. It's somewhat of a blur,</p> <p>9 sir.</p> <p>10 Q. Do you -- before being retained as</p> <p>11 an expert here, did you have an understanding</p> <p>12 that there were non-asbestiform amphiboles?</p> <p>13 A. Probably not in any detail, I think</p> <p>14 would be fair.</p> <p>15 Q. Did you have an understanding of</p> <p>16 what an amphibole was before being retained as</p> <p>17 an expert here?</p> <p>18 A. No. There's some geology, but --</p> <p>19 and, again, other than -- and I've done, you</p> <p>20 know -- I was certainly schooled in organic</p> <p>21 chemistry, et cetera. So, again, I had some</p> <p>22 basic -- you know, some basic fundamental</p> <p>23 science knowledge, probably more than the</p> <p>24 average person; but I don't remember exactly</p> <p>25 what I knew.</p>
<p style="text-align: right;">Page 71</p> <p>1 before being retained as an expert in the case</p> <p>2 here, as to what "asbestiform" meant?</p> <p>3 A. I don't remember exactly the</p> <p>4 gradations of knowledge. I couldn't answer</p> <p>5 that. I think the -- you know, other than</p> <p>6 asbestos, it was a general understanding of</p> <p>7 that. I don't recall exactly the line before</p> <p>8 2016 and after 2016.</p> <p>9 I have done enough, you know, that</p> <p>10 I was in charge of the National Center For</p> <p>11 Toxicological Research -- people don't realize</p> <p>12 that -- at FDA. But I did a lot of</p> <p>13 carcinogeneses research in fundamental</p> <p>14 mechanisms, biological inflammatory, chronic</p> <p>15 inflammatory, the particle-induced. So I mean,</p> <p>16 there was a general understanding, but not more</p> <p>17 than that.</p> <p>18 Q. But to be clear, you're not aware</p> <p>19 of doing any research relating to asbestos</p> <p>20 specifically at the time you were at the</p> <p>21 National Center For Toxicological Research?</p> <p>22 A. I wasn't -- I was in charge of</p> <p>23 that, NCTR, right, in Arkansas. But I did not</p> <p>24 involve myself in any asbestos research.</p> <p>25 Q. Before being retained as an expert</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. Okay. Before being retained as an</p> <p>2 expert in this case, did you have any knowledge</p> <p>3 regarding laboratory testing methodology for</p> <p>4 the presence of asbestos?</p> <p>5 MS. O'DELL: Object to the form.</p> <p>6 THE WITNESS: Not -- only varied --</p> <p>7 only very generally. Not in any great</p> <p>8 form. I'm certainly familiar with the</p> <p>9 different methods before.</p> <p>10 But, again, my answer is the same.</p> <p>11 It's vague of exactly how my knowledge</p> <p>12 evolved by 2016. The general methods</p> <p>13 probably, but I did not spend a lot of</p> <p>14 time on methods; and it wasn't a prime</p> <p>15 subject of my research.</p> <p>16 BY MR. EWALD:</p> <p>17 Q. When you say "a general</p> <p>18 understanding of the different methods," what</p> <p>19 general understanding did you have in 2016?</p> <p>20 A. Well, I mean, I was trained in -- I</p> <p>21 can -- you know, going back to the electron</p> <p>22 microscope, TEM, my undergraduate days,</p> <p>23 et cetera, so I have general knowledge of</p> <p>24 different kinds of methods and as they could</p> <p>25 apply to different kinds of biological agents;</p>



<p style="text-align: right;">Page 74</p> <p>1 but it was a general scientific sense.</p> <p>2 Q. Okay. And so I take it --</p> <p>3 A. I had not studied -- I'm sorry.</p> <p>4 Let me stop there. I apologize.</p> <p>5 Q. I was going to say that the -- am I</p> <p>6 correct that before being retained as an expert</p> <p>7 in this case, you were not aware of any testing</p> <p>8 methods specifically as it relates to asbestos?</p> <p>9 MS. O'DELL: Object to the form.</p> <p>10 THE WITNESS: I don't -- I don't</p> <p>11 recall what I knew exactly before.</p> <p>12 BY MR. EWALD:</p> <p>13 Q. Okay. Before being retained as an</p> <p>14 expert in this case, did you know anything</p> <p>15 about the chemical and geological relationship</p> <p>16 between talc and asbestos?</p> <p>17 A. Not in exquisite form. You know, I</p> <p>18 had some general understanding of basic</p> <p>19 principles but not in specific form.</p> <p>20 Q. What basic principles did you</p> <p>21 understand before 2016 about the chemical and</p> <p>22 geological relationship between talc and</p> <p>23 asbestos?</p> <p>24 A. Well, there was probably some, you</p> <p>25 know -- again, I apologize. I just don't have</p>	<p style="text-align: right;">Page 76</p> <p>1 right?</p> <p>2 A. Well said.</p> <p>3 Q. And you're not a microscopist?</p> <p>4 A. Well, so let's just be careful. I</p> <p>5 am certainly -- you know, how do you want to</p> <p>6 define a "microscopist"?</p> <p>7 You have wonderful -- you and I am</p> <p>8 sure both have qualified experts in all these</p> <p>9 areas. I'm not -- let me see if I can be</p> <p>10 helpful to you.</p> <p>11 I am not your geology, mineralogy,</p> <p>12 microscopist expert, right. My reg -- I can be</p> <p>13 hopefully helpful as the intersection of those</p> <p>14 areas with the regulatory world. But I mean,</p> <p>15 honest, pure geological question, while I had</p> <p>16 in order to understand the regulations, as is</p> <p>17 always is the case, you have to have an</p> <p>18 understanding and study the geology.</p> <p>19 Certainly, other experts should</p> <p>20 testify, I mean, on the geology, mineralogy,</p> <p>21 and microscopy aspects. I do not want to get</p> <p>22 involved.</p> <p>23 As it relates to regulatory</p> <p>24 questions and the opinions I've given, I have</p> <p>25 to be comfortable in that intersection. But</p>
<p style="text-align: right;">Page 75</p> <p>1 a very clear demarcation in my knowledge. I</p> <p>2 mean, I was not -- the one thing -- I mean, I</p> <p>3 had some general understanding of geology. You</p> <p>4 know, I come from a place that had a very</p> <p>5 strong geology history. But the -- there were</p> <p>6 certainly gaps in my understanding prior to</p> <p>7 involvement in this matter.</p> <p>8 Q. When you say you "come from a place</p> <p>9 with a great geology history," where are you</p> <p>10 referring to?</p> <p>11 A. Well, my college. I mean, it has a</p> <p>12 very strong -- some of the great geologists of</p> <p>13 the prior two centuries come from that place.</p> <p>14 You go up -- there was a very significant</p> <p>15 investment in geology as a fundamental science</p> <p>16 it was involved in. But, again, I mean, I was</p> <p>17 on the biological side of that; and there were</p> <p>18 gaps in my understanding.</p> <p>19 Q. Did you take any geology courses in</p> <p>20 college that you can remember?</p> <p>21 A. Not that I -- I took inorganic</p> <p>22 chemical courses.</p> <p>23 Q. And you're not a geologist, right?</p> <p>24 A. I'm not a geologist.</p> <p>25 Q. And you're not a mineralogist,</p>	<p style="text-align: right;">Page 77</p> <p>1 that's been my whole life, and that's been my</p> <p>2 whole training experience.</p> <p>3 Q. Okay. So are you -- I'm not clear.</p> <p>4 Are you suggesting that you are an</p> <p>5 expert in microscopy?</p> <p>6 A. Well, I certainly have an</p> <p>7 understanding of microscopy, a basic</p> <p>8 understanding, right, more than the general</p> <p>9 person. I mean, I've done microscopy. I've</p> <p>10 done, right, but I will -- I'm not going to</p> <p>11 testify on microscopy.</p> <p>12 But obviously, if there's a lab</p> <p>13 test that is regulated by the agency that</p> <p>14 involves microscopy, then I have to understand</p> <p>15 enough to understand that intersection.</p> <p>16 Q. When you say you have a basic</p> <p>17 understanding of microscopy, you've done</p> <p>18 microscopy, what microscopy have you done?</p> <p>19 A. If you want to give me a urine</p> <p>20 sample, I can look and see whether you have a</p> <p>21 bacterial infection. I can do a basic gram</p> <p>22 stain under a -- you know, under a microscope.</p> <p>23 I can look at certain pathological fixated</p> <p>24 slides stained with various chemicals. I have</p> <p>25 done that.</p>

<p style="text-align: right;">Page 78</p> <p>1 Again, sir, I do not want -- I am</p> <p>2 not going to be the microscopist, only to the</p> <p>3 extent that you would expect a physician</p> <p>4 scientist regulator, who is -- I mean, I spend</p> <p>5 my life regulating diagnostic and laboratory</p> <p>6 tests; and microscopy is a part of that.</p> <p>7 The science of microscopy, please</p> <p>8 have other experts. If it relates to FDA and</p> <p>9 diagnostic tests, I'm happy to discuss that.</p> <p>10 Q. Okay. But it's fair to say that</p> <p>11 you have never personally used any testing</p> <p>12 method to attempt to detect the presence of</p> <p>13 asbestos in any media?</p> <p>14 A. That would be fair.</p> <p>15 Q. And it's fair to say that you've</p> <p>16 never witnessed someone else test media for the</p> <p>17 presence of asbestos using a microscopy method?</p> <p>18 A. I reviewed, you know, hundreds and</p> <p>19 hundreds of documents that, I mean, is part of</p> <p>20 the record that involved that. But the answer</p> <p>21 to your question is no. I mean, I have not.</p> <p>22 But I have -- I mean, I am</p> <p>23 certainly comfortable in reading reports that</p> <p>24 result from tests where, the microscopy TEM. I</p> <p>25 mean, that's what I do.</p>	<p style="text-align: right;">Page 80</p> <p>1 clinically trained scientist, doctor about</p> <p>2 that. I don't think I had any more knowledge</p> <p>3 of that, sir.</p> <p>4 Q. Before the last break, you were</p> <p>5 talking about certain things with respect to</p> <p>6 the grinding, crushing, and milling process of</p> <p>7 talc.</p> <p>8 Before being retained as an expert</p> <p>9 in this case, what, if anything, did you know</p> <p>10 about the mining of talc?</p> <p>11 A. I had not spent time studying that</p> <p>12 at all, so I mean, I did not study that. I</p> <p>13 could not tell you the particle size. I could</p> <p>14 not tell you the specifications. I could not</p> <p>15 tell you what the effects were of that process</p> <p>16 before I -- before 2016.</p> <p>17 Q. All right. Are let's talk about</p> <p>18 your process for the work in this case. And I</p> <p>19 want to start with the more recent work you did</p> <p>20 from approximately spring 2023 until today.</p> <p>21 And I guess the question to you is, you were</p> <p>22 asked -- well, let me pause for a moment.</p> <p>23 If you go to paragraph 25 of your</p> <p>24 report please.</p> <p>25 A. Yes, sir.</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. What, if anything, did you know</p> <p>2 about the -- let's put it this way: Before</p> <p>3 being retained as an expert in 2016, what, if</p> <p>4 anything, did you know about talc?</p> <p>5 A. I had a very basic knowledge of</p> <p>6 talc. It was just general knowledge of talc.</p> <p>7 Q. What did you generally understand</p> <p>8 about talc?</p> <p>9 A. I had some general background</p> <p>10 knowledge, and I can't quite remember it. I</p> <p>11 mean, I certainly was aware that there was some</p> <p>12 controversy around talc. I don't think I ever</p> <p>13 dealt with that or studied that controversy.</p> <p>14 But I think that I, you know -- I</p> <p>15 mean, I'll tell you that I lived -- you know,</p> <p>16 again, it's very hard to know exactly in 2016</p> <p>17 what I knew when. My brain just doesn't</p> <p>18 compartmentalize that. But generally, I mean,</p> <p>19 I thought there was a world of asbestos and</p> <p>20 there was a world of talc; and I didn't connect</p> <p>21 them. I never studied the relationship to have</p> <p>22 any real deep appreciation of that.</p> <p>23 Q. All right.</p> <p>24 A. I think I had the general view of,</p> <p>25 you know, the average doc, the average</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. All right. So you say in</p> <p>2 paragraph 25 that "after leaving government</p> <p>3 service in January 2023, I have had the</p> <p>4 opportunity to review more documents discussed</p> <p>5 above." Right?</p> <p>6 A. Yes, sir.</p> <p>7 Q. And is that in part at least</p> <p>8 considered -- referring to paragraphs 12 and 13</p> <p>9 in the preceding pages?</p> <p>10 A. I would have to look, sir. I</p> <p>11 don't --</p> <p>12 Q. Sure.</p> <p>13 A. Sure, sir.</p> <p>14 Q. Okay. And so in paragraph 12 it</p> <p>15 talks about what was available to you,</p> <p>16 including the MDL discovery repository,</p> <p>17 deposition transcripts and exhibits, trial</p> <p>18 testimony and exhibits, all the documents</p> <p>19 available on Johnson &amp; Johnson's website Review</p> <p>20 the Evidence page, it talks about talc, and</p> <p>21 FDA's website, correct?</p> <p>22 A. Yes, sir.</p> <p>23 Q. All right. And then you talk about</p> <p>24 the documents you considered are listed in</p> <p>25 Appendix C. What I'm going to do is -- my</p>



<p style="text-align: right;">Page 82</p> <p>1 understanding is that there was a materials 2 considered list that was included as an 3 appendix in your November 2023 report, right? 4 A. Correct. 5 MR. EWALD: We'll mark that one as 6 Exhibit 6. 7 (Whereupon, Exhibit 6, Reliance 8 List Initial Report, was marked for 9 identification.) 10 BY MR. EWALD: 11 Q. And then there was a First Amended 12 Appendix C For Materials Considered after that, 13 correct? 14 A. Correct. 15 MR. EWALD: We'll mark that as 16 Exhibit 7. 17 (Whereupon, Exhibit 7, First 18 Amended Appendix C Materials Considered, 19 was marked for identification.) 20 MR. EWALD: And then there was a 21 Second Amended Appendix C Materials 22 Considered dated April 1st, 2024. We'll 23 mark that as Exhibit 8. 24 25</p>	<p style="text-align: right;">Page 84</p> <p>1 think, pretty extensively with the frame- -- 2 with the regulatory framework of cosmetics, 3 right. So let's put that -- I mean, I start 4 with that. 5 Q. Okay. 6 A. I start with the basic Food and 7 Drug Regulatory framework, right. And 8 certainly reviewed that again as I reentered 9 here, right. So I wanted to see where I left 10 off. 11 As you can tell -- again, let me 12 just digress a little. The opening report 13 dealt with a few -- besides the statutory 14 framework and what were the general 15 requirements, it dealt with a few of the key -- 16 if my recollection is right, I mean, it based 17 my -- I based the report off some key -- what's 18 the right word -- key sentinel states of 19 pronouncement from the federal government to 20 other agencies. 21 So, for example, if my memory is 22 right, you know, I dealt with -- I looked at 23 the FDA's response in 2014. I looked at IARC. 24 And so there was a general let's look at the 25 record that FDA put in that report. I think I</p>
<p style="text-align: right;">Page 83</p> <p>1 (Whereupon, Exhibit 8, First 2 Amended Appendix C Materials Considered, 3 was marked for identification.) 4 BY MR. EWALD: 5 Q. Is that the most recent materials 6 considered list that you have for this case, 7 sir? 8 A. That all tracks with my 9 understanding, sir. 10 Q. All right. And the materials 11 considered list -- unless I say anything 12 differently, we'll work off of Exhibit 8, which 13 is the second amended. 14 And that one is 84 pages long, 15 correct? 16 A. I take your stipulation. Whatever 17 you stipulate, I'm happy to agree to. 18 Q. Okay. So given your knowledge 19 level of the topics that we discussed before 20 talking about the materials considered, walk me 21 through your process in how you researched the 22 questions that were posed to you in connection 23 with your November 2023 report? 24 A. So I have a number of -- I mean, 25 you start with my -- opening report dealt, I</p>	<p style="text-align: right;">Page 85</p> <p>1 updated it from 2014 to be complete. But I 2 didn't go beyond those, I mean, specific 3 sentinel events that were cited in that opening 4 report. I did that in the beginning in spring 5 of 2023. 6 You know, the first question for me 7 was, well, what's the record here; how do I 8 make sure that I'm looking -- you know, I'm 9 basing opinions on a complete record, 10 recognizing there's no such thing as complete 11 information. 12 I don't think anyone has complete 13 information over a 50-year-history, you know. 14 There is documents, and you only have what's 15 produced and what people can find. So the 16 first question was: What's the evidentiary 17 base of which to look. 18 The thing that I sort of -- what is 19 the right word -- stumbled upon or I saw was, 20 in asking the question what's the record to 21 answer these questions, I found this, you know. 22 In the Facts About Talc there is -- 23 if you put it up -- I think there's a section 24 there called "The Evidence" or something like 25 that where someone for the Johnson &amp; Johnson</p>

<p style="text-align: right;">Page 86</p> <p>1 says here is the evidence, go make up your own 2 mind. And there are a lot of documents. Most 3 of those are trial exhibits, but, again, put 4 together by the defendants. 5 And I think then there were a 6 series of Daubert hearings or whatever. I 7 focused primarily on the underlying documents 8 that were put on by the -- by Johnson &amp; 9 Johnson. So that was the first bucket, as I 10 put in that footnote. 11 And then I asked for access to the 12 entire discovery database. And in that it 13 included all the materials produced as well as 14 there were -- you know, there are many 15 depositions and a lot of other documents that 16 went into that discovery database. So I 17 reviewed the Facts About Talc. I reviewed 18 those documents. 19 And then I did -- a majority of the 20 time would probably be -- you would say would 21 be -- the best way to characterize it is spent 22 searching a database for over the months, that 23 discovery database. 24 Q. Okay. So it's your testimony that 25 the first thing you started researching was</p>	<p style="text-align: right;">Page 88</p> <p>1 it was exactly that. 2 In fact, there were about five or 3 six different sets. You can tell they were 4 D documents or P -- I mean, I'd have to go 5 look. They were marked different ways. So 6 you've got to -- it was clear that they came 7 from a number of different sources. 8 Q. Okay. And so did you conduct any 9 searches in that initial phase of looking at 10 Facts About Talc? 11 A. My first effort that I recall was 12 to go through those documents. 13 Q. When you say "go through those 14 documents," you reviewed every document that 15 talks about talc? 16 A. I attempted to, yes. I attempted 17 to look at every -- that's why my numbers and 18 my hours are relatively high here. I actually 19 wanted to look at -- I mean, I don't want to 20 represent that I studied in detail every 21 document, but my goal was to at least scan 22 every document to the extent that my technology 23 allowed me to do that and my -- the numbers of 24 hours that I had. But I don't want to 25 represent, again, that I studied every</p>
<p style="text-align: right;">Page 87</p> <p>1 going to J&amp;J's Facts About Talc website? 2 A. I'm not sure first. That was 3 certainly right up there. I asked -- I wanted 4 to make sure I had access to, you know, all, 5 you know, what people considered to be the 6 record in this case. I mean, there's no -- so 7 I'm not saying, you know, the records are a 8 vast, you know, concept here; but that seemed 9 to be a good -- again, I don't want to say -- 10 maybe I looked at the discovery database before 11 I looked at the Facts About Talc. I can't tell 12 you exactly the order. 13 But very early on from the 14 beginning, I wanted to see, all right, what is 15 the evidence that the defendants are putting 16 forward in this matter; and it was all there. 17 I mean, it wasn't all there, but there was a 18 lot there. 19 Q. Well, is it your understanding that 20 Facts About Talc includes exhibits admitted at 21 trial by both parties? 22 A. Yes, sir, exactly. I thought that 23 that was a good place to start, right. The 24 fact -- that was the assertion. Here's 25 something, go make up your own mind, right. So</p>	<p style="text-align: right;">Page 89</p> <p>1 document, but I attempted to do that. 2 Q. Okay. And walk me through your 3 process when you're looking at these documents. 4 Are you taking notes along the way? 5 A. You know, thanks to Apple and 6 whatever, we have iPads now; and there's a 7 swipe feature. And my recollection is that I 8 did mark documents. 9 I don't want to get too much into 10 the -- I don't want to cross the line -- let me 11 look at counsel -- of what's processed in 12 preparation of reports, et cetera. 13 MS. O'DELL: We will take the 14 position, John, anything that are his 15 notes that ultimately became part of the 16 report would be work product and be 17 protected as part of drafts of the report. 18 That is my position on that. 19 MR. EWALD: And I, at this point, 20 am not pushing for any of that. I'm 21 trying to understand what exists. 22 BY MR. EWALD: 23 Q. And so without getting into the 24 content of that, you say you marked different 25 documents as you flipped through your iPad.</p>

<p style="text-align: right;">Page 90</p> <p>1 Are you saying you marked -- let me</p> <p>2 put it this way: What did you mean when you</p> <p>3 said you marked the documents on your iPad?</p> <p>4 A. Exactly that. I mean, I used a</p> <p>5 stylist, and I would circle -- I mean, it's</p> <p>6 possible I -- you know, I mean, I actually</p> <p>7 scribbled, right, something on a number of</p> <p>8 those -- on those pages as I was going through</p> <p>9 them. I actually marked those documents --</p> <p>10 marked certain documents.</p> <p>11 Q. All right. So before actually</p> <p>12 going into the discovery database or the Facts</p> <p>13 About Talc website, did you review any, for</p> <p>14 lack of a better word, background documents on</p> <p>15 the topic?</p> <p>16 A. My opening report.</p> <p>17 Q. Okay. And so before going into the</p> <p>18 Facts About Talc or the document discovery</p> <p>19 database, you didn't receive sort of a starter</p> <p>20 pack of materials from plaintiff's counsel</p> <p>21 about the asbestos controversy?</p> <p>22 A. I can tell you I didn't want any</p> <p>23 starter materials.</p> <p>24 Q. Okay.</p> <p>25 A. I mean, I resisted. Now, there may</p>	<p style="text-align: right;">Page 92</p> <p>1 with respect to the MDL document discovery</p> <p>2 database, how did you navigate your way through</p> <p>3 that?</p> <p>4 A. There's a search bar.</p> <p>5 Q. Okay.</p> <p>6 A. Right. And, you know, 40 years of</p> <p>7 experience of searching documents, you know,</p> <p>8 I'm very comfortable, you know. I sometimes</p> <p>9 have a hard time printing those documents. I</p> <p>10 get stumped from those grainy PDFs. But,</p> <p>11 otherwise, I'm comfortable searching terms.</p> <p>12 Q. What sort of search terms do you</p> <p>13 remember entering?</p> <p>14 A. I have probably entered over at</p> <p>15 times hundreds and hundreds of different search</p> <p>16 terms. If there's a subject matter in my</p> <p>17 report, you can look at any page; and I can</p> <p>18 probably tell you in my report, you know,</p> <p>19 generally. These are -- the stuff in my report</p> <p>20 are the stuff that I searched. You can assume</p> <p>21 that key words from these areas are the words</p> <p>22 that I searched.</p> <p>23 Q. Do you have an understanding of</p> <p>24 approximately how many documents are in the MDL</p> <p>25 discovery database?</p>
<p style="text-align: right;">Page 91</p> <p>1 have been -- going back to 2016, you know, I</p> <p>2 may have asked -- you know, in the opening</p> <p>3 report it may have been a little different. I</p> <p>4 may have asked for this CIR ingredient review.</p> <p>5 I may have asked for the citizens' petitions.</p> <p>6 I think I asked for all -- if my</p> <p>7 recollection is right, I asked for all the</p> <p>8 documents that were cited in the 2016 FDA</p> <p>9 response. So there I did ask counsel, but</p> <p>10 not -- I mean, for this -- for the -- for this</p> <p>11 report that you have in front of you. It was</p> <p>12 me and the databases.</p> <p>13 Q. So -- go ahead.</p> <p>14 A. Please.</p> <p>15 Q. When you went to the database, how</p> <p>16 did you navigate your way through there to look</p> <p>17 for documents?</p> <p>18 A. Well, again, there's multiple</p> <p>19 databases, right. So Facts About Talc, Facts</p> <p>20 About Talc -- I'm scrolling through these PDFs</p> <p>21 ultimately or some kind of image, and I'm</p> <p>22 marking them; and I'm swiping.</p> <p>23 Q. And, I'm sorry. I should have been</p> <p>24 clearer. I understand the Facts About Talc.</p> <p>25 What I unartfully meant to ask is,</p>	<p style="text-align: right;">Page 93</p> <p>1 A. Not as many as I would have</p> <p>2 expected.</p> <p>3 Q. Okay. Well, that means you have a</p> <p>4 sense of how many are in there.</p> <p>5 How many do you think are in there?</p> <p>6 A. I can only tell you what's not when</p> <p>7 you're looking for stuff. I mean, this is</p> <p>8 50 years, right. I mean, this is 50 years. So</p> <p>9 I respect that.</p> <p>10 But I'm -- you know, I assume that</p> <p>11 there are millions of documents in that MDL.</p> <p>12 But there are also areas that I couldn't find</p> <p>13 stuff in the discovery database, but I assume</p> <p>14 there's millions. I never actually looked at</p> <p>15 the total count.</p> <p>16 Q. In connection with your searching</p> <p>17 of the MDL and discovery database, at any point</p> <p>18 in time -- I don't want to know the</p> <p>19 specifics -- but at any point in time, did you</p> <p>20 ask counsel for help on, you know, what to look</p> <p>21 for?</p> <p>22 A. What to look for?</p> <p>23 Q. Yes.</p> <p>24 A. Yeah.</p> <p>25 Q. Okay.</p>

<p style="text-align: right;">Page 94</p> <p>1 A. I may have asked counsel if I 2 couldn't print the document or give them a 3 Bates number. I had some problems at some 4 point getting PDF imaging. There's always 5 natives that you get back and sometimes -- so I 6 would ask them to print off documents. Let me 7 just -- I mean, I gave counsel documents. 8 Q. Okay. Let's look at your Second 9 Amended Appendix C, that's Exhibit 8. Let me 10 know when you have it in front of you. 11 A. Thanks, sir. I do. 12 Q. And if you turn to the first page, 13 my understanding from communications with 14 counsel is that the highlighted materials are 15 some of the newer materials that were added to 16 your list. 17 Do you have any understanding of 18 that? 19 A. I do not know exactly the -- what's 20 been communicated. I leave it to counsel to 21 represent exactly what was done here. I can 22 tell you what I did. 23 Q. First of all, do you -- have you 24 seen a version of this where certain entries 25 are highlighted in yellow?</p>	<p style="text-align: right;">Page 96</p> <p>1 conversations, but I was literally 2 dictating to counsel or to legal staff 3 what documents I had -- at that period of 4 time, had looked at; and I wanted to make 5 sure it was on the list. So I would tell 6 staff those. 7 And at one point I -- again, I 8 don't want to waive anything -- I said, 9 hey, just make sure to the other side, 10 they know -- I don't want them to have to 11 go through the whole list and have to go 12 search for everything again. So I mean, 13 that was the import of that. 14 BY MR. EWALD: 15 Q. If you also flip through this, 16 leaving aside the yellow highlighting, there 17 are some materials that are bolded. 18 Do you know anything about that, 19 why they are bolded? 20 A. No, I have no idea. Again, I did 21 not -- not at all. Well, I have no idea how -- 22 certainly, nothing from my perspective has any 23 significance. 24 Q. If we look at page 2 -- this isn't 25 the only place that you identify it -- but</p>
<p style="text-align: right;">Page 95</p> <p>1 A. I see that. But, again, I leave 2 this -- the whole production of the considered 3 list to counsel. I do see it, and I'm aware of 4 it. And certainly, my goal -- 5 Q. Do you have -- I'm sorry. 6 Do you have an understanding of 7 the -- 8 MS. O'DELL: I think he wasn't 9 finished. 10 BY MR. EWALD: 11 Q. Sorry. 12 A. So my -- I'm sorry. I apologize. 13 Let me just answer your question. 14 Q. Sure. 15 A. Just ask, again, your question. 16 Q. My question was: Do you have an 17 understanding of what the yellow highlighting 18 is intending to represent? 19 MS. O'DELL: I will just represent 20 that by counsel that there was an effort 21 to identify newly added materials so it 22 would be apparent to you and others for 23 the defense. 24 THE WITNESS: So I can add -- and, 25 again, I don't want to get into</p>	<p style="text-align: right;">Page 97</p> <p>1 there are a number of depositions listed there. 2 Do you see that? 3 A. Correct. 4 Q. We talked about the Facts About 5 Talc website. We talked about the document 6 discovery database. 7 How did you go about identifying 8 deposition and exhibits to review? 9 A. So there are, if I'm correct -- I 10 have to double check this -- the discovery -- I 11 have to go back and double check this and see 12 which database. I believe the discovery 13 database has depositions in there and exhibits, 14 but I'd have to go back and double check that. 15 So there were clearly -- so these 16 were searched, I mean, at different points in 17 time. And if I'm correct, I did amass 18 depositions in some kind of folder and just 19 searched them generally as I searched the whole 20 documents. So if I was searching a term, I 21 would want to search the depositions too. 22 Certain depositions I read, you 23 understand. But the majority of the time I'm 24 searching, I'm searching these documents. 25 Q. And you mentioned the -- I believe</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 that there was a folder that was amassed with a</p> <p>2 number of these deposition transcripts.</p> <p>3 How was that folder -- how were the</p> <p>4 depositions collected into that folder?</p> <p>5 A. They're downloaded and put in and</p> <p>6 moved in. And I kept -- I mean, I would</p> <p>7 sometimes save documents and download them.</p> <p>8 And there were occasional times where I asked</p> <p>9 counsel could you send me in one place all the</p> <p>10 exhibits to a deposition.</p> <p>11 Q. So --</p> <p>12 A. I mean, I would have the</p> <p>13 deposition, but I could -- but as I'm reading</p> <p>14 the deposition, I said could you send me the</p> <p>15 bucket of all the exhibits that were attached</p> <p>16 to that.</p> <p>17 Q. As you sit here today, can you</p> <p>18 recall any instance in which you asked counsel</p> <p>19 for help on identifying depositions for you to</p> <p>20 review?</p> <p>21 MS. O'DELL: I object to that</p> <p>22 question. You're asking for the content</p> <p>23 of his conversations with counsel. I</p> <p>24 think that's beyond what's appropriate.</p> <p>25 MR. EWALD: Well, to the extent</p>	<p style="text-align: right;">Page 100</p> <p>1 exhibits"?</p> <p>2 A. Yes.</p> <p>3 Q. Who is Matt Sanchez?</p> <p>4 A. So Sanchez, I believe, is the one</p> <p>5 of the principals I think, if I'm right, at</p> <p>6 RJ Lee.</p> <p>7 Q. Okay. And how did you decide to</p> <p>8 review all of his deposition and trial</p> <p>9 testimony exhibits?</p> <p>10 MS. O'DELL: Object to the form.</p> <p>11 THE WITNESS: I was probably</p> <p>12 reading some kind of trial transcript and</p> <p>13 some testimony in trying to understand</p> <p>14 testing. And I wanted to understand -- I</p> <p>15 wanted to understand everything he was</p> <p>16 saying.</p> <p>17 BY MR. EWALD:</p> <p>18 Q. Okay. Did you -- in your review of</p> <p>19 trial transcripts, did you review any attorney</p> <p>20 opening or closing statements?</p> <p>21 A. Possibly. Possibly. I think, you</p> <p>22 know -- I mean, I have to go back. I have some</p> <p>23 recollection at some point of Ms. Brown</p> <p>24 maybe -- I mean, I think -- I forget exactly,</p> <p>25 but I was interested in seeing what defense was</p>
<p style="text-align: right;">Page 99</p> <p>1 that you're -- you, as counsel, are</p> <p>2 providing materials to your expert, I</p> <p>3 believe that's clearly within the bounds</p> <p>4 of Rule 26. And so I guess maybe I will</p> <p>5 slightly rephrase and see if you like this</p> <p>6 one.</p> <p>7 BY MR. EWALD:</p> <p>8 Q. Dr. Kessler, did counsel provide</p> <p>9 you with any of the deposition transcripts that</p> <p>10 you reviewed?</p> <p>11 A. I may have asked for certain</p> <p>12 volumes. I mean, I -- one thing I am not good</p> <p>13 at, I get very confused. I mean, I remember</p> <p>14 was -- you know, how many days was this</p> <p>15 deposition, and I get all the days of this</p> <p>16 deposition, et cetera.</p> <p>17 So, yes, counsel did provide me</p> <p>18 with depositions because, I mean, I would see a</p> <p>19 deposition or whatever. But there was --</p> <p>20 sometimes there are multiple depositions, and I</p> <p>21 got confused. Yes, counsel provided me with</p> <p>22 depositions.</p> <p>23 Q. What about on the page 3, the next</p> <p>24 page over, do you see where it says, "All</p> <p>25 Matthew Sanchez deposition and trial testimony</p>	<p style="text-align: right;">Page 101</p> <p>1 saying.</p> <p>2 Q. All right. And when you say in</p> <p>3 your materials considered "All Matthew Sanchez</p> <p>4 depositions and trial testimony exhibits," does</p> <p>5 that mean "all"?</p> <p>6 A. No. Nothing in life means "all,"</p> <p>7 right. I mean, I -- I tried to, you know -- I</p> <p>8 certainly wouldn't want to represent that I</p> <p>9 have every deposition and every testimony, but</p> <p>10 it was -- I mean, I asked counsel specifically</p> <p>11 on Sanchez can I have all the exhibits and can</p> <p>12 I have the various testimonies.</p> <p>13 And, again, my recollection is</p> <p>14 that -- I mean, I was getting confused what</p> <p>15 gets -- what is this testimony here. Is it</p> <p>16 getting played in here? So I'm not sorting</p> <p>17 that out.</p> <p>18 I just wanted to -- I wanted to</p> <p>19 understand what Dr. Sanchez was saying. So I</p> <p>20 mean, that was important to me.</p> <p>21 Q. Okay. And so you did receive some</p> <p>22 testimony from plaintiff's counsel?</p> <p>23 A. I certainly -- my recollection is I</p> <p>24 know I asked for it. My tendency -- what's on</p> <p>25 the top of my head is I asked for exhibits. I</p>



<p style="text-align: right;">Page 102</p> <p>1 rarely -- I wanted the exhibits in one place. 2 If I had a deposition or a trial testimony, I 3 wanted the exhibits to be able to review 4 simultaneously, right. 5 It's -- also, I'm sure, you know, 6 for convenience, I said can I get, you know, 7 all of Dr. Sanchez's testimony, all days of 8 that. I don't remember exactly what I said 9 along the way. 10 Q. Just above that a couple of lines, 11 it says, "All expert reports filed in this 12 matter on November 15, 2023." 13 Do you see that? 14 A. Yes. 15 Q. And did you review all of the 16 expert reports filed in this matter on 17 November 15, 2023? 18 A. I had them made available to me, I 19 believe, in a folder. And, again, I mean, the 20 reports that were done prior to -- let me be 21 exact here. 22 There were reports that were not 23 available to me that were submitted 24 simultaneously with my report, right. You 25 asked -- we are now looking at the Second</p>	<p style="text-align: right;">Page 104</p> <p>1 THE WITNESS: Could I just ask you 2 for my sheet? 3 I think there's a sheet with that 4 report. I can pull up exactly. I think 5 it is a referred to as the Third Amended 6 Report. I don't have the date in my head. 7 BY MR. EWALD: 8 Q. That's fine. 9 A. Actually, I do have it. Thank you. 10 I do. It's dated November 17, 2023. 11 Q. All right. So you said -- I don't 12 mean to put words in your mouth. 13 Is that what you reviewed recently? 14 A. It is certainly something that I 15 asked for after my report. 16 Q. And what do you understand -- well, 17 first of all, what, if at all, do you rely on 18 Longo 3 for in connection with your opinions in 19 this case? 20 A. So the only thing that I -- in 21 Longo 3, I don't rely on anything in Longo 3. 22 Q. Okay. Why is that? 23 A. Because my report was dated before 24 I read Longo 3. 25 Q. So there's nothing that you</p>
<p style="text-align: right;">Page 103</p> <p>1 Amended Complaint, right. My report goes in 2 end of last year. And I did ask for -- and I 3 have the -- the expert reports in a folder -- 4 can you let me download so if there's anything 5 I want to look at. And that was -- that was 6 after my report. 7 Q. And so what did you look at amongst 8 expert reports? 9 A. I can't tell you. I don't have a 10 recollection of every -- I mean, for example -- 11 I mean, I did look at Longo 3 after my report 12 was done. That's one that I remember looking 13 at. 14 But, again, you know, I remember 15 studying -- is it Laura Webb? I can't tell you 16 when I looked at what of hers along the way, 17 but I was very interested in what she had said. 18 Q. Okay. When you say "Longo 3," is 19 that -- you're talking about -- what are you 20 talking about when you say "Longo 3"? 21 A. So I mean, I believe there was -- I 22 mean, he has a third report. And I have it 23 pasted on -- I forget the date. I mean, I 24 think that was probably the report that got -- 25 I don't want to guess.</p>	<p style="text-align: right;">Page 105</p> <p>1 reviewed after issuance of your report that you 2 are relying on for your opinions in this case? 3 MS. O'DELL: Object to the form. 4 THE WITNESS: From Dr. Longo that 5 I'm relying on? I mean -- 6 BY MR. EWALD: 7 Q. No. I'm asking more generally. I 8 asked you why you're not relying on Longo 3. 9 You said it was issued after your November 2023 10 report, correct? 11 A. Yeah. There's nothing that -- 12 there's none of my opinions that I'm relying on 13 Dr. Longo. There is nothing inconsistent here, 14 I mean, with Dr. Longo; but there's nothing, 15 right. 16 And I do cite -- I mean, you know, 17 I am generally aware and, you know, he's a 18 world-class expert and will testify. And 19 there's nothing I'm saying that I don't think 20 anything inconsistent, but I am not relying on 21 him. He is an expert; I am an expert. 22 Q. What is your basis for you saying 23 he is a world-class expert? 24 A. Well, I think that there is, you 25 know, I mean, a career dedicated to studying in</p>

<p style="text-align: right;">Page 106</p> <p>1 depth these matters. I went back, you know --</p> <p>2 I think, if I'm correct -- I mean, he goes back</p> <p>3 to the -- I think he goes -- if you pull up his</p> <p>4 CV -- I would have to have it in front of me --</p> <p>5 but it's a relatively distinguished CV.</p> <p>6 I have no disagreements, no</p> <p>7 certainly -- but I am not relying on him, sir.</p> <p>8 He is an expert. And I am just -- again, I'm</p> <p>9 just an expert. I tend to -- there are</p> <p>10 occasional times in my -- when I testify where</p> <p>11 I will rely on an expert, just to be clear so</p> <p>12 you understand, where my opinion is</p> <p>13 necessitated or based on certain facts of</p> <p>14 another expert, right; or I will make</p> <p>15 assumptions based on another expert. I am not</p> <p>16 making any assumption based on Dr. Longo or</p> <p>17 anything like that.</p> <p>18 He is not -- you know, he is not</p> <p>19 necessary for any of my opinions. Again,</p> <p>20 please full respect, full -- you know, no</p> <p>21 disagreement. Don't read that I have any</p> <p>22 distance or anything like that. That is not</p> <p>23 the case. I'm just not relying on him as I am</p> <p>24 using that word.</p> <p>25 Q. Do you consider Dr. Sanchez, Matt</p>	<p style="text-align: right;">Page 108</p> <p>1 those are distractions.</p> <p>2 If you want me to -- if you are</p> <p>3 pulling me in, I'm happy to be responsive.</p> <p>4 BY MR. EWALD:</p> <p>5 Q. But are you referring to the</p> <p>6 Region 9 discussions --</p> <p>7 A. That is one thing that is cited.</p> <p>8 But, again, I think -- you know, again, I think</p> <p>9 that's noise in the system. I am trying not to</p> <p>10 pay attention to it.</p> <p>11 Q. I appreciate that. And more</p> <p>12 broadly, though, do you have the expertise to</p> <p>13 make a conclusion that you think that</p> <p>14 Dr. Longo's conclusions are correct on testing</p> <p>15 and mineralogy and Sanchez's are wrong?</p> <p>16 A. I think you have to -- again, I</p> <p>17 didn't say that. Those are your words,</p> <p>18 correct.</p> <p>19 Q. I didn't say you said that. I</p> <p>20 didn't say you said that. It's a question.</p> <p>21 A. Do I have the expertise?</p> <p>22 So it is, again, what's very</p> <p>23 important here, what I think is -- what is</p> <p>24 central here is the context of this, right.</p> <p>25 The repeated statements over 50 years that no</p>
<p style="text-align: right;">Page 107</p> <p>1 Sanchez, a world-class expert?</p> <p>2 A. You know, I'm sure -- again, I have</p> <p>3 not studied his CV or looked at it. I have</p> <p>4 nothing to -- again, I think there is a</p> <p>5 complicated history with RJ Lee. I don't want</p> <p>6 to get into it here.</p> <p>7 So let me just not -- unless you</p> <p>8 want me to get into that, you know, I have no</p> <p>9 opinions. I don't think it's important to this</p> <p>10 matter. I was very interested in the facts</p> <p>11 that he -- you know, what he was saying.</p> <p>12 Q. Okay. And so what I'm hearing you</p> <p>13 say is that you do think Dr. Longo is a</p> <p>14 world-class expert, but not Dr. Sanchez; is</p> <p>15 that what you're saying?</p> <p>16 MS. O'DELL: Object to the form.</p> <p>17 Misstates his testimony.</p> <p>18 THE WITNESS: Yeah. I -- my -- if</p> <p>19 you want to get into it, I'm happy to --</p> <p>20 there were issues, very strong</p> <p>21 disagreements between certain government</p> <p>22 agencies and RJ Lee. I don't want to</p> <p>23 implicate Mr. Sanchez in them. There is</p> <p>24 references to the RJ Lee. Again, I'd like</p> <p>25 to stay away from that. I think that</p>	<p style="text-align: right;">Page 109</p> <p>1 asbestos was ever found in any sample is just</p> <p>2 not credible in my view.</p> <p>3 And if you look at what happened</p> <p>4 here, you would expect that certain samples</p> <p>5 would have evidence of asbestos. Longo is</p> <p>6 consistent with that.</p> <p>7 And I am happy to go through in</p> <p>8 detail what I think, you know; and I think it's</p> <p>9 the central aspect, right. You don't take talc</p> <p>10 from Vermont, right, and process it with that</p> <p>11 kind of knowledge about the basic geology,</p> <p>12 subject it to Raymond rollers and forces and</p> <p>13 not have the effect on the type of fibers that</p> <p>14 you would expect -- that should be expected</p> <p>15 there.</p> <p>16 That and what Dr. Longo did, right,</p> <p>17 despite 50 years of what I think are statements</p> <p>18 that are troublesome in light of the evidence,</p> <p>19 I mean, he persisted as, you know, I mean,</p> <p>20 others before him, right, in trying to</p> <p>21 understand, right, what the public health risk</p> <p>22 was. And I think that was -- in the face of</p> <p>23 50 years of absolute denial, it was not</p> <p>24 credible. I think this is one of the most</p> <p>25 important public health stories. I mean, I</p>



<p style="text-align: right;">Page 110</p> <p>1 think it's right up there.</p> <p>2 Q. Okay. And so you do realize that</p> <p>3 during the entire time that Dr. Longo was doing</p> <p>4 what you described was being paid as a</p> <p>5 plaintiff expert, correct?</p> <p>6 A. I'm being paid as a plaintiff's</p> <p>7 expert, sir. I think I can actually do your</p> <p>8 company and your client -- to be honest, all I</p> <p>9 can do is tell you what I see. And that's all</p> <p>10 Dr. Longo can tell you, what he sees, right.</p> <p>11 But I can tell -- let me -- let me finish the</p> <p>12 answer to my question -- to your question.</p> <p>13 Q. Yes, sir.</p> <p>14 A. Okay. What -- what I see is in the</p> <p>15 face of documents, right, that evidence of</p> <p>16 fibers, asbestos fibers, asbestiform fibers,</p> <p>17 were in talc. And in the face of processes</p> <p>18 that any -- if you think about it, you know,</p> <p>19 grind this up to 10 microns, right, put it</p> <p>20 through meshes of minus 325, send it -- if you</p> <p>21 get a positive, send it to a different</p> <p>22 laboratory, the variability between -- the lack</p> <p>23 of reliability between these laboratories, the</p> <p>24 sensitivity, I calculate at 14 percent.</p> <p>25 And to be able to have -- to state</p>	<p style="text-align: right;">Page 112</p> <p>1 do that today.</p> <p>2 But make no mistake. I am very</p> <p>3 confident, right, of my ability. And, again,</p> <p>4 I'm only as good as what the records show.</p> <p>5 But when you look at that record</p> <p>6 and you apply some basic scientific regulatory</p> <p>7 principles and you just look at the document,</p> <p>8 to go in in 1972 or '73 and tell FDA no</p> <p>9 asbestos when you have Dr. Hutchinson,</p> <p>10 et cetera, saying there is TEM and not playing</p> <p>11 the agency straight, that is something that</p> <p>12 should not have been done. And that is</p> <p>13 specifically within my expertise.</p> <p>14 I know a misleading statement when</p> <p>15 I see it, right, based on the evidence.</p> <p>16 Q. All right. So we have been going</p> <p>17 for about an hour and 15. It is also here on</p> <p>18 the east coast almost noon. I am willing to do</p> <p>19 whatever on the timing wise and lunch break and</p> <p>20 everything else, Doctor. I'm also sensitive,</p> <p>21 again, to the court reporter's needs to make</p> <p>22 sure she gets a good record.</p> <p>23 So with that, let's go off the</p> <p>24 record. And we can talk about what we are</p> <p>25 going to do next.</p>
<p style="text-align: right;">Page 111</p> <p>1 no asbestos ever in front of the agency both in</p> <p>2 1976 and in 2016, over 50 years, that's just</p> <p>3 not credible.</p> <p>4 Q. What expertise do you have to reach</p> <p>5 the conclusion that in 50 years of no asbestos</p> <p>6 was not credible?</p> <p>7 What specific expertise in your</p> <p>8 background, beyond reviewing documents in this</p> <p>9 litigation, do you have to reach that</p> <p>10 conclusion, sir?</p> <p>11 A. I have led some of the most</p> <p>12 important investigations on scientific</p> <p>13 regulatory matters in this country. Your</p> <p>14 company knows that, okay. And I have done</p> <p>15 that. I have done that. That is what I am</p> <p>16 good at.</p> <p>17 I can sit here if you'd like -- and</p> <p>18 I'm prepared to tell you, your company, your</p> <p>19 board, what I see, right. But it's not</p> <p>20 credible, right, to say that there's never been</p> <p>21 asbestos here over 50 years. And I am happy to</p> <p>22 show you the steps, right, that I put together.</p> <p>23 I'm only as good as what the evidence shows.</p> <p>24 And I'm happy to do that in detail with you.</p> <p>25 That's what my report does. And I'm happy to</p>	<p style="text-align: right;">Page 113</p> <p>1 (Whereupon, a break was taken.)</p> <p>2 BY MR. EWALD:</p> <p>3 Q. Doctor, can you make sure you have</p> <p>4 your amended report in front of you?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And if you could go to</p> <p>7 paragraph 67 on page 18.</p> <p>8 A. I'm there.</p> <p>9 Q. Okay.</p> <p>10 A. 67?</p> <p>11 Q. Yes, sir. In that paragraph you</p> <p>12 state, "In my opinion, once JNJ had evidence of</p> <p>13 a) the presence of asbestos because of its</p> <p>14 known carcinogenicity and absence of a</p> <p>15 threshold dose; or b) the presence of</p> <p>16 non-asbestiform amphiboles or fibrous talc, the</p> <p>17 safety of their product was not established."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And so is it your -- are you</p> <p>21 offering the opinion that J&amp;J talc products</p> <p>22 historically contained asbestos?</p> <p>23 A. There is no doubt in my mind that</p> <p>24 J&amp;J products, based on the record, contained</p> <p>25 asbestos.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. Okay. And when you talk about 2 under b) "the presence of non-asbestiform 3 amphiboles," is that the -- does that mean that 4 non-asbestiform amphiboles of any size and 5 shape? 6 A. I don't draw a distinction. 7 Q. Okay. And is it your opinion 8 that -- well, do you have on the first one a) 9 about the presence of asbestos, I take it under 10 that opinion you also believe that J&amp;J's talc 11 products have been misbranded? 12 A. I don't want to -- I don't want to 13 give a legal opinion, okay. I just want to be 14 careful that I'm not giving a legal opinion. 15 Because you have not substantiated -- I think 16 the answer was because you have not 17 substantiated safety and didn't have that 18 statutory warning, that safety was not 19 established. That would probably be a 20 misbranding charge. 21 Q. Okay. And so I'm trying to 22 understand as to how you're framing it in your 23 mind, that you feel it is -- is it appropriate 24 to -- you feel it is not appropriate to offer 25 an opinion on whether certain parts of</p>	<p style="text-align: right;">Page 116</p> <p>1 strongly in '72, but I'm not saying it doesn't 2 exist earlier. 3 Q. All right. Is it your opinion that 4 the presence of non-asbestiform amphiboles in 5 Johnson &amp; Johnson talc powders render them 6 misbranded? 7 A. Let me just look at my report. 8 Certainly J&amp;J did not substantiate the safety. 9 I mean, there is a lot of controversy 10 surrounding non-asbestiform amphiboles, and J&amp;J 11 did not substantiate the safety of their -- of 12 that product. I am certainly saying that in 13 this paragraph. 14 Q. Okay. But is it your testimony 15 that the presence of non-asbestiform amphiboles 16 in Johnson &amp; Johnson talc is an adulterant? 17 A. I would want to -- I just would 18 want to search for -- do me a favor. If you 19 would be so kind -- I can search for it -- go 20 to that paragraph. I want to be precise. 21 Can someone point me to the 22 paragraph where I use the word "adulterated"? 23 I want to be precise on what I have 24 concluded. I can do it. I want to be exactly 25 precise on that because you're asking me.</p>
<p style="text-align: right;">Page 115</p> <p>1 21 CFR §740.10 have been complied with but not 2 necessarily whether or not 21 USC §361 has 3 been? 4 A. No. I'm not drawing that 5 distinction. I just want to be careful, you 6 know, what's a legal opinion and what's not. I 7 don't think it is the ultimate legal opinions 8 in this case. I mean, I think that I made it 9 very clear if this product contains asbestos, 10 it would be adulterated and the lack of the 11 warning would make it misbranded. 12 Q. What about -- well, do you have a 13 particular time, a particular year in which you 14 say that this is when J&amp;J talc products began 15 being misbranded? 16 A. I think that there is evidence 17 certainly beginning in 1972. I mean, I don't 18 give a -- I don't have a formal opinion. I 19 have not ascribed a time period to this. I 20 think that certainly there is evidence 21 beginning in 1972, if not before, where there 22 is strong evidence of the existence of 23 chrysotile in Vermont talc that would make the 24 product adulterated and, therefore, misbranded. 25 So I see that, you know, pretty</p>	<p style="text-align: right;">Page 117</p> <p>1 Just for the record, I'm searching 2 the report. I just want to see the paragraph 3 that you're referring to. 4 Q. I appreciate you telling us that's 5 what you're doing. 6 A. So I mean, I state exactly the way 7 139 is phrased. I don't want to -- I base it 8 on the totality of the evidence. I don't 9 believe I -- I say it is specifically 10 non-asbestiform amphiboles, the totality of the 11 evidence. 12 Q. Okay. So if I ask you do you have 13 an opinion whether or not J&amp;J's talc products 14 were misbranded because they contain -- well, 15 withdrawn. 16 Do you have an opinion as to 17 whether or not J&amp;J's talc products were 18 adulterated because of the presence of 19 non-asbestiform amphiboles? 20 Your answer is you don't have one? 21 MS. O'DELL: Object to the form. 22 Mischaracterizes the testimony. 23 THE WITNESS: I apologize. 139 24 goes to adulteration, and let me just 25 find -- let me do this again.</p>

<p style="text-align: right;">Page 118</p> <p>1 You're asking me now on -- and, 2 again, I think my opinion on adulteration 3 is based on the totality of the evidence 4 that I think the product is adulterated. 5 Let me just see where I conclude in 6 a paragraph -- if anyone has it, I will 7 find it -- where it has any conclusion on 8 misbranded in the report. For some reason 9 I am not pulling it up. 10 Let me just go further. I have to 11 go -- again, if you can point me to where 12 my opinion that I'm saying it is 13 misbranded, I just want to -- I would 14 appreciate it. 15 BY MR. EWALD: 16 Q. And my last question, which was 17 related to adulterated -- I think I understand 18 your position. We may get back to misbranded. 19 Let's turn to page 22 paragraph 78? 20 A. Yes. Thank you, sir. Give me a 21 second. Thank you, sir. 22 Q. Okay. And so we have here a 23 definition of asbestos, and you give a 24 definition of asbestos. 25 Is that your definition of asbestos</p>	<p style="text-align: right;">Page 120</p> <p>1 MR. EWALD: Okay. 2 MS. O'DELL: So I am not on camera 3 because I am choosing not to be. I am not 4 on camera because my camera is broken. 5 THE WITNESS: I'm -- 6 MR. EWALD: Hold on. I'm not 7 suggesting anything improper -- 8 MS. O'DELL: Excuse me. Let me be 9 clear. You know well enough, having been 10 in depositions with me before, I've always 11 been on camera. So this is a technical 12 problem. It is not a choice. 13 THE WITNESS: And I was -- 14 MR. EWALD: I'm sorry. 15 Dr. Kessler, one other thing, and then you 16 can respond. 17 I was noting -- again, I will make 18 the record very clear. I am not 19 suggesting any ill intent as to 20 Ms. O'Dell. It is purely that any -- my 21 concern I have would be alleviated. And 22 now I see your face, and so all is well. 23 BY MR. EWALD: 24 Q. And, Dr. Kessler, if you have 25 something you want to say, you are welcome to</p>
<p style="text-align: right;">Page 119</p> <p>1 that you are using when you use the term in 2 this report? 3 A. I can pull up a -- I have a sheet 4 here that probably has maybe 50 different 5 definitions of asbestos. I am happy to go 6 through all of them. This is not my definition 7 of asbestos. I think I am comfortable with 8 J&amp;J's definition in paragraph 79, which is what 9 I've been generally using is 79. 10 Q. Okay. I am going to ask some more 11 questions, and I'm not suggesting anything at 12 all improper; but there's been a number of 13 times where Dr. Kessler has looked to his left, 14 which is where Ms. O'Dell is -- 15 A. I'm sorry -- 16 Q. Let me make my record. 17 I can't see Ms. O'Dell's face. I'm 18 not suggesting that anything improper is going 19 on, but it would be a heck of a lot better if I 20 can see Ms. O'Dell's face. 21 MS. O'DELL: John, as I mentioned, 22 my camera wasn't working. And so I've had 23 somebody bring an external camera to me in 24 the last few minutes. And I'm trying to 25 problem solve that right now.</p>	<p style="text-align: right;">Page 121</p> <p>1 say it too. 2 A. Just so you understand the 3 geography of the room, I have -- I am 4 distracted -- I have five screens in front of 5 me, okay. I have an iPad with the realtime. I 6 have three monitors. I have -- so my eyes are 7 right and left. 8 Anyway, Ms. O'Dell, if she wanted 9 to send me a signal, she would probably kick me 10 under the table. That was a joke, for the 11 record. 12 But it's just -- my eyes are being 13 distracted because I have the realtime right 14 here. So I'm looking at that. If I'm looking 15 to my left, that's between Ms. O'Dell and me. 16 MS. O'DELL: Let me say, for the 17 record, I have a camera on top of my 18 laptop. And if it falls, I have not 19 fallen, it's just the camera. So I am 20 just problem solving here. 21 MR. EWALD: I appreciate it. I 22 don't think there is any actual thing 23 going on. I just wanted to make sure of 24 that. So I appreciate people working with 25 that.</p>

<p style="text-align: right;">Page 122</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Now back to the questions.</p> <p>3 Doctor, when we had the</p> <p>4 discussion we just had, you had talked about a</p> <p>5 list in front of you of 50 different</p> <p>6 definitions of asbestos; is that what you said?</p> <p>7 A. No. I have a list to my right.</p> <p>8 And I am happy to pull all the -- you know,</p> <p>9 there's a glossary -- I think it was done by</p> <p>10 the National Geological Service -- of different</p> <p>11 definitions over the decades of asbestos to the</p> <p>12 point where you asked me what is my definition</p> <p>13 of asbestos.</p> <p>14 Q. Okay. And so what I want to know</p> <p>15 is: When you use the term "asbestos" in the</p> <p>16 report without any citation to a specific</p> <p>17 source, what definition of asbestos are you</p> <p>18 using?</p> <p>19 A. Again, you have to be a little</p> <p>20 careful, again, because sometimes the word</p> <p>21 "asbestos" is used in a document, I mean, you</p> <p>22 have to look at what the person who wrote the</p> <p>23 document is referring to.</p> <p>24 But I think we can -- I mean, I am</p> <p>25 comfortable with 79.1 as a definition.</p>	<p style="text-align: right;">Page 124</p> <p>1 I am happy to discuss -- let me</p> <p>2 look at this whole list.</p> <p>3 I'm sure it probably comes -- so I</p> <p>4 am happy to show you Figures 18 through 27</p> <p>5 definitions of asbestos in regulatory over</p> <p>6 the years; and I don't know whether I took</p> <p>7 it from this list, but it was, you know, a</p> <p>8 respected government agency. And I took</p> <p>9 the defendants -- I think you can pick</p> <p>10 many different -- I think it's a credible</p> <p>11 definition early on.</p> <p>12 I don't give it any more import</p> <p>13 than anything else. I am very comfortable</p> <p>14 with J&amp;J's definition.</p> <p>15 BY MR. EWALD:</p> <p>16 Q. You also cite in your report to</p> <p>17 IARC 2010, correct?</p> <p>18 A. Well, there -- there are decisions</p> <p>19 in IARC. I could do 2010 and 2012, I believe;</p> <p>20 both talc not containing asbestos, asbestiform</p> <p>21 fibers, and then talc with. So I cite to a</p> <p>22 number of IARC documents.</p> <p>23 THE WITNESS: Could I have my IARC</p> <p>24 sheets, please?</p> <p>25 Thank you.</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Okay. And let's start, though,</p> <p>2 with when you gave the definition of asbestos,</p> <p>3 you used IARC 1973, correct?</p> <p>4 A. No, I don't think I did. I used</p> <p>5 the word "defined" -- the first time I used the</p> <p>6 definition -- well, I did definition -- I list</p> <p>7 IARC, but I give J&amp;J's use of the word they</p> <p>8 defined. There is a general discussion what</p> <p>9 they designate it.</p> <p>10 But then I used J&amp;J -- I've always</p> <p>11 used the J&amp;J that was on J&amp;J's specs,</p> <p>12 et cetera, and I've always used that. That's</p> <p>13 what I mean, I think.</p> <p>14 Q. Okay. So are you suggesting that</p> <p>15 what occurs in paragraph 78 is not a definition</p> <p>16 that you include of asbestos in your report?</p> <p>17 A. No. Of course it's there. I don't</p> <p>18 think there's anything very controversial about</p> <p>19 that. But I'm telling you a very succinct</p> <p>20 definition is in 79.1.</p> <p>21 Q. And why, though, in 78 did you</p> <p>22 choose 1973 IARC for the asbestos definition?</p> <p>23 A. I was searching for --</p> <p>24 THE WITNESS: Do me a favor. Can I</p> <p>25 get my list of asbestos definitions?</p>	<p style="text-align: right;">Page 125</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Okay. And so can you explain to me</p> <p>3 why you chose a 50-year-old definition of</p> <p>4 asbestos for IARC when you had one from 2010,</p> <p>5 for example, from IARC?</p> <p>6 A. I don't see any -- I see it -- to</p> <p>7 be honest, I see 78 and 79 as very consistent.</p> <p>8 So I mean, there is no specific rationale.</p> <p>9 If you look at -- and, in fact, if</p> <p>10 you look at the 2012 definition, I think that</p> <p>11 '73 definition, 2012 definition -- we can go</p> <p>12 look at it -- I think is cited in 2012.</p> <p>13 Q. What about this, do you have --</p> <p>14 A. IARC cites -- in IARC's 2012, you</p> <p>15 know, that covers both, you know, asbestiform</p> <p>16 talc, asbestos talc without -- it uses -- in</p> <p>17 the sentence there, it says, "Asbestos is the</p> <p>18 generic commercial designation for a group of</p> <p>19 naturally occurring mineral silicate fibers of</p> <p>20 the serpentine and amphibole series. These</p> <p>21 include the serpentine mineral chrysotile also</p> <p>22 known as" -- I guess they added "white asbestos</p> <p>23 and the five amphibole minerals actinolite,"</p> <p>24 blah, blah, "and tremolite."</p> <p>25 And then they cite, open</p>

<p style="text-align: right;">Page 126</p> <p>1 parentheses, "(IARC 1973 USGS 2001)." So</p> <p>2 IARC -- this is -- that is the definition that</p> <p>3 IARC was using for over 50 years; and used it</p> <p>4 again in 2012, as I see it.</p> <p>5 Q. Let's look at IARC 2010, which is</p> <p>6 on -- it's mentioned in your report, correct?</p> <p>7 And if we go to --</p> <p>8 MS. O'DELL: John, would you put</p> <p>9 that in the chat, please.</p> <p>10 MR. EWALD: Yes.</p> <p>11 Jake, please put it in chat.</p> <p>12 THE WITNESS: Could someone else</p> <p>13 hand me the full document from 2010, the</p> <p>14 full document?</p> <p>15 MR. KEESTER: Just checking. It is</p> <p>16 D-280, right, John?</p> <p>17 MR. EWALD: Yeah.</p> <p>18 MR. KEESTER: Okay. Sending.</p> <p>19 BY MR. EWALD:</p> <p>20 Q. Okay. Doctor, I'm looking at the</p> <p>21 Talc Not Containing Asbestiform Fibres Exposure</p> <p>22 Data Introduction. It's page 277.</p> <p>23 A. Got it.</p> <p>24 Q. IARC 280. And there at the bottom.</p> <p>25 Hold on.</p>	<p style="text-align: right;">Page 128</p> <p>1 one that matches, IARC '73, IARC 2012, J&amp;J for</p> <p>2 50 years has a definition; and that was the one</p> <p>3 that I felt most comfortable with. I am happy</p> <p>4 to discuss the merits of the 2010 one. I</p> <p>5 didn't -- I used the one that was in place for</p> <p>6 50 years.</p> <p>7 Q. Are you comfortable discussing the</p> <p>8 merits of IARC 2010 and whether or not it is an</p> <p>9 appropriate definition of asbestos?</p> <p>10 A. If you want to spend the next two</p> <p>11 hours, we can spend, you know, the -- discuss</p> <p>12 the merits of using the terminology and the</p> <p>13 semantics and the complexities of using</p> <p>14 something like asbestiform. I am happy to do</p> <p>15 that.</p> <p>16 Q. My question, going line by line,</p> <p>17 sir -- I think your answer is -- you don't have</p> <p>18 an opinion one way or another about whether or</p> <p>19 not the first sentence I read to you is</p> <p>20 correct: "Asbestos is a commercial term that</p> <p>21 describes six minerals that occur in the</p> <p>22 asbestiform habit: actinolite, anthophyllite,</p> <p>23 chrysotile, grunerite, riebeckite and</p> <p>24 tremolite."</p> <p>25 Do you agree with that, sir?</p>
<p style="text-align: right;">Page 127</p> <p>1 Do you see where it starts with</p> <p>2 asbestos?</p> <p>3 A. Yes, sir.</p> <p>4 Q. Okay. "Asbestos is a commercial</p> <p>5 term that describes six minerals that occur in</p> <p>6 the asbestiform habit: actinolite,</p> <p>7 anthophyllite, chrysotile, grunerite,</p> <p>8 riebeckite and tremolite (IARC, 1977)."</p> <p>9 Do you agree with that statement,</p> <p>10 Doctor?</p> <p>11 A. I agree that you read that</p> <p>12 correctly. I don't have an opinion on whether</p> <p>13 I agree with that statement. IARC uses a</p> <p>14 different statement in 2012 that I do cite in</p> <p>15 '73. So the '73 matches the 2012.</p> <p>16 I am happy to spend -- I don't have</p> <p>17 an opinion specifically on that statement.</p> <p>18 Q. Well, you don't have an opinion as</p> <p>19 to which is the appropriate definition of</p> <p>20 asbestos?</p> <p>21 A. I'm not -- again, as I said, there</p> <p>22 are 50 different definitions that are recorded</p> <p>23 by the National Geological Survey. I am happy</p> <p>24 to put those in the record.</p> <p>25 The one that I am very comfortable,</p>	<p style="text-align: right;">Page 129</p> <p>1 MS. O'DELL: Object to the form.</p> <p>2 THE WITNESS: I think I have</p> <p>3 answered the question. The definition</p> <p>4 that I am using is the IARC definition</p> <p>5 that is cited in 2012, and it was cited in</p> <p>6 1973. That's the definition that I am</p> <p>7 most comfortable using.</p> <p>8 BY MR. EWALD:</p> <p>9 Q. Why is that, sir?</p> <p>10 What is the scientific basis for</p> <p>11 that, sir?</p> <p>12 A. It's the -- the scientific basis of</p> <p>13 that is, you know, you're asking me -- the word</p> <p>14 asbestiform is close to Vicastinon [sic]</p> <p>15 concept as far as semantics. I mean, the</p> <p>16 scientific basis is scientifically, you know,</p> <p>17 the word "fibrous I" could understand.</p> <p>18 Asbestiform has, obviously, a long</p> <p>19 condition; but I certainly -- J&amp;J's definition</p> <p>20 is fibrous, serpentine, chrysotile, and fibrous</p> <p>21 forms of the amphophile I think have great</p> <p>22 scientific merit. And that's been in place for</p> <p>23 50 years. And that, again, I'm very</p> <p>24 comfortable aligning myself with J&amp;J's</p> <p>25 definition and IARC's '73 and 2012.</p>



<p style="text-align: right;">Page 130</p> <p>1 Obviously, IARC must have had some</p> <p>2 reason for changing -- to use different</p> <p>3 terminology between 2010 and 2012. But the '73</p> <p>4 that I cite is what IARC does in 2012, and I am</p> <p>5 comfortable with that.</p> <p>6 Q. Okay. By the way, in talking about</p> <p>7 whether asbestiform is a scientific merit as a</p> <p>8 term, you have reached this opinion after not</p> <p>9 even knowing what it was before being retained</p> <p>10 as an expert in this case?</p> <p>11 A. I don't think -- let me just look</p> <p>12 at your statement. If you go back, tell me</p> <p>13 where I said I didn't know about asbestiform.</p> <p>14 MS. O'DELL: Excuse me.</p> <p>15 Suzanne, I had objected to the</p> <p>16 question. I don't know if you heard me,</p> <p>17 but I want to make sure that my objection</p> <p>18 is noted for the record.</p> <p>19 MR. EWALD: The record will reflect</p> <p>20 what the record reflects here.</p> <p>21 BY MR. EWALD:</p> <p>22 Q. So let's go to the second sentence,</p> <p>23 "Similarly to talc, these six minerals occur</p> <p>24 more commonly in a non-asbestiform habit, and</p> <p>25 may also be elongated without being</p>	<p style="text-align: right;">Page 132</p> <p>1 without being asbestiform."</p> <p>2 Do you agree with that?</p> <p>3 MR. O'DELL: Object to the form.</p> <p>4 Asked and answered.</p> <p>5 THE WITNESS: I could not have been</p> <p>6 more explicit on what my definition is.</p> <p>7 There should be no complexity on what</p> <p>8 definition I am using.</p> <p>9 BY MR. EWALD:</p> <p>10 Q. How does your definition differ</p> <p>11 from this one, sir?</p> <p>12 A. I don't see that as a definition.</p> <p>13 It doesn't say define. J&amp;J's definition in</p> <p>14 79.1 gives you a definition. It says,</p> <p>15 "Asbestos is defined."</p> <p>16 I don't read your sentence that you</p> <p>17 read as asbestiform is defined as -- the</p> <p>18 sentence you just read, that is just a general</p> <p>19 statement. I don't see the word "definition"</p> <p>20 in that sentence at all.</p> <p>21 Where is that definition?</p> <p>22 Q. Let's take that definition.</p> <p>23 Do you agree with the statement</p> <p>24 that "Similarly to talc, these six minerals</p> <p>25 occur more commonly in a non-asbestiform habit,</p>
<p style="text-align: right;">Page 131</p> <p>1 asbestiform."</p> <p>2 Do you agree with that sentence?</p> <p>3 MS. O'DELL: Okay. Do you have</p> <p>4 that in front of you, Dr. Kessler?</p> <p>5 Can you see it.</p> <p>6 THE WITNESS: I actually have my</p> <p>7 own copy of this. So just -- I mean, I</p> <p>8 was able to pull that. I mean, I would</p> <p>9 appreciate the whole report, if someone</p> <p>10 could get me the whole document so we can</p> <p>11 make sure I'm looking at the whole</p> <p>12 document.</p> <p>13 I think that's a complicated</p> <p>14 sentence. I think there's a lot of</p> <p>15 complexity to that sentence. Again, I'm</p> <p>16 happy to discuss or happy to look at what</p> <p>17 the geologist and mineralogist discuss.</p> <p>18 BY MR. EWALD:</p> <p>19 Q. Well, you are the one who is using</p> <p>20 the term "asbestos" throughout the report, and</p> <p>21 I want to know what you mean when you use it.</p> <p>22 And so I want to know whether or not you agree</p> <p>23 with IARC 2010 that, "Similarly to talc, these</p> <p>24 six minerals occur more commonly in a</p> <p>25 non-asbestiform habit and may also be elongated</p>	<p style="text-align: right;">Page 133</p> <p>1 and may also be elongated without being</p> <p>2 asbestiform"?</p> <p>3 Do you agree with that, whether it</p> <p>4 is a definition or not?</p> <p>5 A. I certainly agree that the first, I</p> <p>6 think, is a very factual question, right. You</p> <p>7 would have to give me what the writer's</p> <p>8 definition of asbestiform that is used by IARC</p> <p>9 in order for me to tell you whether I agree</p> <p>10 with that or not.</p> <p>11 Q. Well, what is the definition of</p> <p>12 "asbestiform" that you use?</p> <p>13 A. There again, I -- I define my terms</p> <p>14 asbestos. I don't believe I set out an</p> <p>15 asbestiform definition. I think that is more</p> <p>16 appropriately discussed by the geologist and</p> <p>17 mineralogist, and I think that's part of the</p> <p>18 semantic -- semantics over the last 50 years.</p> <p>19 Q. Okay. So it's your view that it is</p> <p>20 appropriate for you to define what asbestos is,</p> <p>21 but asbestiform is something that's outside of</p> <p>22 your area of expertise?</p> <p>23 MS. O'DELL: Object to the form.</p> <p>24 Misstates his testimony.</p> <p>25 THE WITNESS: You're way off, sir.</p>

<p style="text-align: right;">Page 134</p> <p>1 And please don't characterize me like</p> <p>2 that. Okay?</p> <p>3 BY MR. EWALD:</p> <p>4 Q. I'm trying to understand what your</p> <p>5 testimony is. Your testimony, you said --</p> <p>6 A. Well --</p> <p>7 Q. Hold on, sir. The question is not</p> <p>8 pending yet. I will tell you what the question</p> <p>9 is. And you said I think that it is more</p> <p>10 appropriate that the asbestiform, that</p> <p>11 definition is something that is dealt with by</p> <p>12 the mineralogist and geologist; and that is a</p> <p>13 semantic argument.</p> <p>14 That's what you said, sir, right?</p> <p>15 A. I responded to your question when</p> <p>16 you asked me what the definition was of</p> <p>17 asbestos, okay. You're asking me for the</p> <p>18 definition of asbestos, was your question. I</p> <p>19 gave you the definition of asbestos.</p> <p>20 You wanted me to use this sentence</p> <p>21 as the definition of asbestos, and I resisted</p> <p>22 because I didn't think it was either meant by</p> <p>23 IARC -- I think you are twisting those words,</p> <p>24 right. And -- and I am using -- the definition</p> <p>25 couldn't be more clear.</p>	<p style="text-align: right;">Page 136</p> <p>1 A. I certainly have read documents</p> <p>2 that have used the word asbestiform.</p> <p>3 Q. And so what -- when you read that</p> <p>4 word, what meaning do you ascribe to it?</p> <p>5 A. It depends what the writer meant by</p> <p>6 it. If you go back and look at -- and I'm</p> <p>7 happy to provide you with a cite. The National</p> <p>8 Geological Service has a glossary, a couple</p> <p>9 of -- all where it has probably 20 pages of</p> <p>10 definitions of asbestiform used by different</p> <p>11 people over time that have been defined in</p> <p>12 different characteristics by different</p> <p>13 definitions.</p> <p>14 So you've got to tell me who -- it</p> <p>15 has to be read in context. You have to know</p> <p>16 who's writing it, what definition they're using</p> <p>17 over the 50 years. There's been many</p> <p>18 definitions. I refer to that National</p> <p>19 Geological Survey glossary.</p> <p>20 Q. Well, when you are going through a</p> <p>21 document and it says asbestiform and it doesn't</p> <p>22 define it, how do you decide what the writer</p> <p>23 meant?</p> <p>24 A. You try to look at context, sir.</p> <p>25 Q. Okay. And what kind of context do</p>
<p style="text-align: right;">Page 135</p> <p>1 I mean -- I mean, if you're the</p> <p>2 chrysotile or you're the fibrous, one of those</p> <p>3 five minerals, that's, in my view, asbestos.</p> <p>4 Q. Okay. And so I will have more</p> <p>5 questions about asbestos definitions, but for</p> <p>6 now I want to know what your definition of</p> <p>7 asbestiform is.</p> <p>8 And am I correct you don't have</p> <p>9 one?</p> <p>10 MS. O'DELL: Object to the form.</p> <p>11 Misstates his testimony.</p> <p>12 THE WITNESS: I don't believe in</p> <p>13 my -- I don't believe that I offer the</p> <p>14 definition of asbestiform in my testimony.</p> <p>15 I would have to double check --</p> <p>16 BY MR. EWALD:</p> <p>17 Q. So --</p> <p>18 A. -- with my --</p> <p>19 Q. Go ahead.</p> <p>20 Without -- so, sir, when you</p> <p>21 read -- well, withdrawn.</p> <p>22 Am I correct that you have read</p> <p>23 documents, over the 830 hours that you've spent</p> <p>24 on this second report, that have used the word</p> <p>25 asbestiform?</p>	<p style="text-align: right;">Page 137</p> <p>1 you look for?</p> <p>2 A. You try to look at the rest of the</p> <p>3 paper. You try to look at the era that it's</p> <p>4 written in. You try to look at the other words</p> <p>5 just as you try to ascribe meaning to any word.</p> <p>6 Q. Okay. So tell me how does the era</p> <p>7 depend on what asbestiform means?</p> <p>8 MS. O'DELL: John, would you mind</p> <p>9 repeating the question please?</p> <p>10 I didn't catch the first part.</p> <p>11 MR. EWALD: What I understood from</p> <p>12 Dr. Kessler is that one of the areas of</p> <p>13 context is era.</p> <p>14 BY MR. EWALD:</p> <p>15 Q. So what I want to know: How does</p> <p>16 the era help impact the context of what</p> <p>17 asbestiform means?</p> <p>18 A. If you look at the National</p> <p>19 Geological Survey glossary, you will see by</p> <p>20 different categories, different dates, right,</p> <p>21 there are different definitions of asbestiform,</p> <p>22 right, that have been utilized, that different</p> <p>23 people have used; and meaning was ascribed at</p> <p>24 different times.</p> <p>25 Again, I am not going to sit here</p>



<p style="text-align: right;">Page 138</p> <p>1 as an expert on the historical use of the word</p> <p>2 asbestiform. I don't represent myself as that.</p> <p>3 Q. But you are an expert on</p> <p>4 understanding the historical use of asbestos?</p> <p>5 MS. O'DELL: Object to the form.</p> <p>6 THE WITNESS: I am an expert on</p> <p>7 when it comes to the regulatory interface</p> <p>8 of carcinogens, potential carcinogens, in</p> <p>9 products that are used under the</p> <p>10 jurisdiction of the Federal Food Drug and</p> <p>11 Cosmetic Act.</p> <p>12 BY MR. EWALD:</p> <p>13 Q. I believe you said that use of the</p> <p>14 term "asbestiform" is semantics; is that right?</p> <p>15 MS. O'DELL: Object to the form.</p> <p>16 That's not what his testimony was.</p> <p>17 THE WITNESS: Every word has a</p> <p>18 semantic derivation.</p> <p>19 BY MR. EWALD:</p> <p>20 Q. What do you mean by that?</p> <p>21 A. Well, I mean, there -- there --</p> <p>22 there's meaning to describe -- can I get -- if</p> <p>23 you have -- I don't have it with me -- the</p> <p>24 NGS Glossary, right.</p> <p>25 I mean, by definition, language and</p>	<p style="text-align: right;">Page 140</p> <p>1 A. I mean, there are -- there are</p> <p>2 certainly statements from that.</p> <p>3 Q. Okay. And these --</p> <p>4 MR. EWALD: Can I have the IWG --</p> <p>5 my IWG page, please?</p> <p>6 Let's see here.</p> <p>7 Thank you very much.</p> <p>8 BY MR. EWALD:</p> <p>9 Q. Okay. I want to put up here on the</p> <p>10 screen -- and this is a cite to this December</p> <p>11 2021 white paper from the Interagency Working</p> <p>12 Group on asbestos throughout your report,</p> <p>13 right?</p> <p>14 A. Put that in the chat.</p> <p>15 MS. O'DELL: Yeah. You read my</p> <p>16 mind.</p> <p>17 John, are you marking this as an</p> <p>18 exhibit?</p> <p>19 And if so, I suppose this is</p> <p>20 Exhibit 9. And then put it in the chat.</p> <p>21 MR. EWALD: We'll mark it as nine.</p> <p>22 Thank you.</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 139</p> <p>1 the -- how -- I mean, the fact that the word</p> <p>2 asbestiform can have different definitions</p> <p>3 among the gee -- in that history and in that</p> <p>4 glossary by definition is a -- is in the field</p> <p>5 of semantics and have meaning.</p> <p>6 Q. And so is it your opinion, then,</p> <p>7 that it is -- it's not important to you to</p> <p>8 understand what semantics means because it's --</p> <p>9 it's changed in your view over time?</p> <p>10 MS. O'DELL: Object to the form.</p> <p>11 THE WITNESS: No. I --</p> <p>12 MS. O'DELL: Excuse me.</p> <p>13 Misstates his testimony.</p> <p>14 THE WITNESS: No, not at all.</p> <p>15 BY MR. EWALD:</p> <p>16 Q. Okay. So let's look at -- you</p> <p>17 spent a lot of time in your report quoting</p> <p>18 from -- well, a lot of time -- you spend a</p> <p>19 number a paragraphs quoting from the FDA white</p> <p>20 paper 2021, right?</p> <p>21 A. There -- there are a lot of</p> <p>22 different portions of that. There's a 2020.</p> <p>23 There's the appendices, the white paper. Yes,</p> <p>24 I do do that.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 141</p> <p>1 (Whereupon, Exhibit 9, White Paper:</p> <p>2 IWGACP Scientific Opinions on Testing</p> <p>3 Methods For Asbestos in Cosmetic Products</p> <p>4 Containing Talca Bates labeled P-2318</p> <p>5 through P-2318_030, was marked for</p> <p>6 identification.)</p> <p>7 MR. EWALD: And this one, Jake, is</p> <p>8 P-2318.</p> <p>9 MR. KEESTER: I just put it in.</p> <p>10 MR. EWALD: Yes.</p> <p>11 MR. KEESTER: And, John, really</p> <p>12 quick, did we mark D-280 as an exhibit?</p> <p>13 MR. EWALD: No. It's okay. I</p> <p>14 don't want -- oh, we'll mark it. Why not?</p> <p>15 We'll mark D-280 IARC 2010, if the</p> <p>16 court reporter doesn't mind, we'll mark</p> <p>17 that as 9, and apologies.</p> <p>18 And then we'll do Exhibit 10 the</p> <p>19 IWGACP 2021 document.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 142</p> <p>1 (Whereupon, Exhibit 10, World 2 Health Organization International Agency 3 for Research on Cancer, IARC Monographs on 4 the Evaluation of Carcinogenic Risks to 5 Humans, Volume 93, Carbon Black, Titanium 6 Dioxide, and Talc, was marked for 7 identification.) 8 BY MR. EWALD: 9 Q. Okay. 10 A. What you put in front of me 11 includes the appendices? 12 I just want to make sure. 13 Q. I can get there, yeah. But right 14 now I'm going to show you the body of it. 15 A. Yeah. 16 Q. You reviewed the appendices, right? 17 A. And -- and the appendices and the 18 2020 document, yeah. 19 Q. Okay. 20 MS. O'DELL: Doctor, are you okay 21 with that, or do we need to put it on the 22 big screen? 23 THE WITNESS: No. I -- yeah. I -- 24 I won't -- I'm fine. Thank you, ma'am. 25 I have these documents in front of</p>	<p style="text-align: right;">Page 144</p> <p>1 didn't bring 24 with me. 2 MS. O'DELL: Okay. 3 THE WITNESS: You can just show 24, 4 Mr. Ewald. That's fine. 5 BY MR. EWALD: 6 Q. Well, I'm happy you can see that 7 what we have on the other pages is more 8 definitions. I'm asking you about the 9 definition of asbestiform, which states, "A 10 specific variety of a mineral or a type of 11 mineral fibrosity associated with a unique 12 fibrous habit of crystal growth, in which the 13 fibers are long and thin, that possess high 14 tensile strength and flexibility. This unique 15 habit of growth is observed in fibrous 16 serpentine chrysotile and certain fibrous 17 amphophile minerals." 18 Do you agree with that definition 19 of asbestiform, sir, by the FDA? 20 MS. O'DELL: Object to the form. 21 THE WITNESS: So -- so let's be 22 clear. IWGACP is not FDA. Right. I 23 mean, I think can we agree on that. Those 24 are individuals in their individual 25 capacity. But it was not a recognized FDA</p>
<p style="text-align: right;">Page 143</p> <p>1 me. I -- I -- I brought them. 2 BY MR. EWALD: 3 Q. All right. So we're here in the 4 glossary of terms section, page 25 of the main 5 document. I want you to look at the 6 Interagency Working Group definition of 7 asbestiform there -- 8 A. I -- I don't -- I don't have that. 9 Can I get that, and can I get a 10 hard copy of that, please? 11 MS. O'DELL: Yes. I will -- we 12 will get -- 13 THE WITNESS: Yeah. I -- I have 14 the white paper I have in front of me, 15 through 23; and I have the appendices. 16 But could you show me what page 17 you're -- you're -- where you are? 18 You're in the glossary at terms -- 19 BY MR. EWALD: 20 Q. Yeah. Glossary of terms -- 21 A. Just so you can show me the index, 22 send me the table of contents so I can see 23 where 16 is in the contents, what page. 24 You're -- now, I stopped printing 25 at 23. So I apologize. I didn't bring -- I</p>	<p style="text-align: right;">Page 145</p> <p>1 document. I think it's so cited, right. 2 So you want to ask the question 3 again? 4 BY MR. EWALD: 5 Q. Sure. I'm more than happy, if 6 you're consistent with that one. 7 So are -- you agree with the 8 Interagency Working Group white paper 9 definition of asbestiform that I just read to 10 you and that appears on page 25 of the December 11 2021 white paper we have marked as Exhibit 10? 12 A. I -- I think that is, again, one 13 definition that is advanced here that cites 14 Campbell. I am not sure. That's how they 15 define, so they're entitled to define it any 16 way they want, and that's what I mean by 17 "semantics." 18 But it's not that I agree or 19 disagree with the definition. That's their 20 definition. That's how they're using the term. 21 Again, if you -- if you refer to -- you know, 22 if you refer to the National Geological Survey, 23 there are other definitions of this asbestos 24 that are used. I don't find anything -- you 25 know, I'm not going to object to this --</p>

<p style="text-align: right;">Page 146</p> <p>1 there's nothing that I'm going to say is wrong</p> <p>2 or I'm going to jump up and down; but I'm</p> <p>3 defining it. That's their definition.</p> <p>4 Q. What expertise do you have to make</p> <p>5 a determination as to whether or not one</p> <p>6 definition of asbestiform is better than</p> <p>7 another?</p> <p>8 A. I -- what I can do is, again, in</p> <p>9 the regulatory context, okay, of reaching a</p> <p>10 decision what -- how a substance should be</p> <p>11 regulated under the act, right, the question is</p> <p>12 to be able to bring basic, you know, scientific</p> <p>13 and medical knowledge and what is -- you know,</p> <p>14 how it gets applied in that framework.</p> <p>15 I'm -- I'm not sure, you know --</p> <p>16 I'm not sure when you say how do you have</p> <p>17 scientific expertise, they define it like that.</p> <p>18 That's how they're using the word -- again,</p> <p>19 welcome to the -- you know, there's a whole</p> <p>20 field of philosophy that deals with the</p> <p>21 question of how you decide what definition</p> <p>22 applies to what word here.</p> <p>23 Q. Well, I -- my question was: What</p> <p>24 expertise do you have and you agree with me</p> <p>25 that mineralogists and geologists have</p>	<p style="text-align: right;">Page 148</p> <p>1 the problems that we've encountered over</p> <p>2 the last 50 years, right.</p> <p>3 So I don't see -- I mean, as far as</p> <p>4 whether asbestos -- asbestiform is meant</p> <p>5 to imply that it has health hazards,</p> <p>6 right, that should be ceded to the</p> <p>7 mineralogists and geologists alone.</p> <p>8 BY MR. EWALD:</p> <p>9 Q. Yeah. I'm not sure exactly I</p> <p>10 understand what you were saying, but --</p> <p>11 A. I'm happy to explain it again.</p> <p>12 Q. No. What I -- what I -- what I</p> <p>13 want to --</p> <p>14 MS. O'DELL: I'm sorry, John. I'm</p> <p>15 not sure if he was finished with his</p> <p>16 answer. Excuse me.</p> <p>17 MR. EWALD: He was -- he was</p> <p>18 finished with his answer, and then he said</p> <p>19 he'd explain it again; and I said no, he</p> <p>20 doesn't need to explain it again. So --</p> <p>21 MS. O'DELL: Let's pause just for a</p> <p>22 moment.</p> <p>23 Dr. Kessler, were you finished with</p> <p>24 your answer?</p> <p>25 If so, that's fine. If you are</p>
<p style="text-align: right;">Page 147</p> <p>1 expertise to offer an opinion as to whether or</p> <p>2 not the definition of asbestiform is an</p> <p>3 accurate one; do you agree with that?</p> <p>4 MR. O'DELL: Object to the form.</p> <p>5 THE WITNESS: Bingo. I think</p> <p>6 you've just put your -- your finger on an</p> <p>7 essential point, right.</p> <p>8 That is what mineralogists and</p> <p>9 geologists don't have is the ability to</p> <p>10 decide if you are going to link that term,</p> <p>11 asbestiform, right, with a health hazard,</p> <p>12 right, or how it should be regulated under</p> <p>13 the act, right, that's the key here,</p> <p>14 right.</p> <p>15 I mean, if you look at the</p> <p>16 definitions that were used and what</p> <p>17 happened here is you see certain</p> <p>18 epidemiological studies that link asbestos</p> <p>19 in -- with hazards, right; and then you</p> <p>20 have certain groups of individuals, right,</p> <p>21 looking and redefining things not in the</p> <p>22 context of the broader expertise, right,</p> <p>23 and being able -- linking it to what that</p> <p>24 ultimate health hazard is.</p> <p>25 And I think that's one of the --</p>	<p style="text-align: right;">Page 149</p> <p>1 not, then please continue.</p> <p>2 THE WITNESS: I think Mr. Ewald</p> <p>3 understands the -- the point that I was</p> <p>4 making.</p> <p>5 The -- if asbestiform is in that</p> <p>6 terminology meant to have any -- to be</p> <p>7 informative in a regulatory sense of</p> <p>8 whether it is hazardous or potential --</p> <p>9 whether it presents a risk, right, that</p> <p>10 definition, then, is not under -- should</p> <p>11 not be under the purview of people who</p> <p>12 don't have the expertise on the public</p> <p>13 health side of your question.</p> <p>14 It can't be set by the</p> <p>15 mineralogists and geologists alone.</p> <p>16 That's fine if they're living in a world</p> <p>17 of just geology. But if, ultimately, in</p> <p>18 the regulatory context, right, you're --</p> <p>19 you're asking the issue of whether there's</p> <p>20 potential human health implications,</p> <p>21 right, that goes broader than just the</p> <p>22 mineralogists and geologists. That's the</p> <p>23 problem with terms that were defined as --</p> <p>24 by the mineralogists and geologists and</p> <p>25 used in ways that increase the specificity</p>

<p style="text-align: right;">Page 150</p> <p>1 but decrease the sensitivity of the</p> <p>2 analysis that have -- in the laboratory</p> <p>3 tests that have implications for human</p> <p>4 health and FDA regulation.</p> <p>5 BY MR. EWALD:</p> <p>6 Q. Okay. So I want to make sure I</p> <p>7 understand.</p> <p>8 You are suggesting that the -- the</p> <p>9 white paper, the Interagency Working Group that</p> <p>10 defines asbestiform and defines asbestos is not</p> <p>11 the appropriate one to use in the regulatory</p> <p>12 context but is, in fact, should be used the</p> <p>13 definition of an internal J&amp;J document?</p> <p>14 MS. O'DELL: Objection. Misstates</p> <p>15 his testimony.</p> <p>16 THE WITNESS: Yeah. Yeah. So</p> <p>17 you're -- you're missing this entirely.</p> <p>18 BY MR. EWALD:</p> <p>19 Q. I'm sure I am.</p> <p>20 A. What I'm saying, and I apologize if</p> <p>21 I'm not clear.</p> <p>22 I actually applaud the Interagency</p> <p>23 Working Group where people with diverse</p> <p>24 backgrounds and expertise that's -- and that's</p> <p>25 what FDA does and FDA brings together those</p>	<p style="text-align: right;">Page 152</p> <p>1 this language, right, elongated -- elongate</p> <p>2 particles, I mean, are -- had the biological</p> <p>3 activity. And we've been caught up in language</p> <p>4 in semantics for, in essence, for 50 years; and</p> <p>5 they're trying to clarify what has biological</p> <p>6 activity. And I applaud that.</p> <p>7 Q. Okay.</p> <p>8 MS. O'DELL: John, are you frozen?</p> <p>9 MR. EWALD: Nope.</p> <p>10 MS. O'DELL: Okay. Sorry.</p> <p>11 MR. EWALD: No. No worries.</p> <p>12 MS. O'DELL: We've had some blips</p> <p>13 on the internet today. I thought there</p> <p>14 was a problem.</p> <p>15 MR. EWALD: No problem at all. I</p> <p>16 was deciding where to go next.</p> <p>17 Let's -- okay. Let's mark as</p> <p>18 Exhibit 11 -- Jake, it's going to be</p> <p>19 Exhibit 8179. If you can drop it in the</p> <p>20 chat, please, this relates to -- the</p> <p>21 highlighting -- it's not mine, but it's</p> <p>22 reflected as highlighting on the document.</p> <p>23 BY MR. EWALD:</p> <p>24 Q. And, Doctor, you --</p> <p>25 MS. O'DELL: Hey, John, give us</p>
<p style="text-align: right;">Page 151</p> <p>1 people in the various subject matter experts of</p> <p>2 various government agencies to be able to deal</p> <p>3 with these complex questions.</p> <p>4 What I am objecting to -- and I</p> <p>5 think they -- they certainly have good faith</p> <p>6 and came up with a definition that they can,</p> <p>7 you know -- they've listed it in their</p> <p>8 glossary.</p> <p>9 I don't think mineralogists and</p> <p>10 geologists -- they certainly can define the</p> <p>11 terms in their -- their field. What they can't</p> <p>12 do is set the terms to have any meaning when it</p> <p>13 comes to implications for public health, right.</p> <p>14 So if there's fibers that are meant</p> <p>15 to be asbestiform or not asbestiform or we're</p> <p>16 going to define these as asbestiform and these</p> <p>17 as non-asbestiform, and they make those</p> <p>18 definitions based on geological and</p> <p>19 mineralogical principles, right, and</p> <p>20 morphological and microscopic characteristics,</p> <p>21 those have to be correlated and validated on</p> <p>22 the human health risk side.</p> <p>23 And I think that was the -- the</p> <p>24 great effort of the Interagency Working Group</p> <p>25 tried to do and basically said get rid of all</p>	<p style="text-align: right;">Page 153</p> <p>1 just a moment here. Excuse me for</p> <p>2 interrupting.</p> <p>3 Could you put it in the chat</p> <p>4 where -- Dr. Kessler has it on the screen.</p> <p>5 It's quite small. So we want to put it on</p> <p>6 a larger screen so he can see it.</p> <p>7 MR. EWALD: Sure. Jake, will get</p> <p>8 it in there in a second.</p> <p>9 MS. O'DELL: Give us a moment to</p> <p>10 download it and put it on the screen.</p> <p>11 (Whereupon, Exhibit 11, Johnson &amp;</p> <p>12 Johnson Consumer Products, Inc.,</p> <p>13 Authorization for Interim Specification,</p> <p>14 Bates labeled JNJMX68_000000438 through</p> <p>15 JNJMX68_000000441, was marked for</p> <p>16 identification.)</p> <p>17 MS. O'DELL: Okay. So Dr. Kessler,</p> <p>18 do you mind if I -- you can click on it</p> <p>19 and see if it will open it up for you.</p> <p>20 You may need to download it onto your</p> <p>21 desktop, and then you'll need to go back</p> <p>22 to your desktop and open it.</p> <p>23 THE WITNESS: It's not -- it's not</p> <p>24 fresh --</p> <p>25 (Discussion held off the record.)</p>

<p style="text-align: right;">Page 154</p> <p>1 MS. O'DELL: John, I'm going to 2 help him a little bit here. 3 MR. EWALD: Of course. 4 (Discussion held off the record.) 5 THE WITNESS: I didn't save it. 6 It's not on my -- it's saved in documents. 7 I want to switch it to desktop, and then I 8 have to -- 9 MS. O'DELL: Okay. 10 THE WITNESS: Where is that 11 document? 12 Thank you. Thank you. 13 MS. O'DELL: Do you want it over 14 there? 15 THE WITNESS: Yeah. Over there 16 would be perfect. Thank you so much. 17 I'm looking to my left now. 18 MS. O'DELL: Okay. You're in 19 control, and you have your mouse. 20 THE WITNESS: Thank you so much. 21 MS. O'DELL: All right. 22 THE WITNESS: Thank you. 23 BY MR. EWALD: 24 Q. All right. Doctor, in that same 25 page of your report, 79.1, you're referring to</p>	<p style="text-align: right;">Page 156</p> <p>1 Vague. 2 THE WITNESS: Yeah. And I think 3 that word "vague" is also probably 4 applicable to my answer. 5 Can I have my testing folder, my -- 6 my testing sheets? 7 I think -- let me tell you what -- 8 it's -- it's well-summarized I think -- 9 actually, if you have something called Rio 10 Tinto -- my Rio Tinto slides, there's an 11 excellent -- well, I mean, there's a slide 12 by Rio Tinto that summarizes the use of 13 various testing. Let me get it. Give me 14 a second. 15 There's -- there's something that 16 says TEM. Margaret -- just give me a 17 second please. There's a TEM. I 18 apologize. Let me just get it here. 19 It gives a chronology of what was 20 in place when -- I have a slide -- again, 21 just give me a second -- that has exactly 22 when was -- when what was used and when 23 TEM really was -- started to come in 24 place. 25 It may be here. Could you just</p>
<p style="text-align: right;">Page 155</p> <p>1 what you call J&amp;J's definition of asbestos. 2 And what I'm showing you, for the 3 record, we'll mark as Exhibit 11. This is -- 4 it has a Bates Number JNJMX68_000000439 as -- 5 it is the Authorization for Interim 6 Specification. 7 A. Got it. 8 Q. "Subject: Cyprus Windsor Minerals 9 Corporation Grade 66 Talc." 10 Do you see that? 11 A. I know this, yes. 12 Q. All right. And under Material 13 Specification, "Properties &amp; Requirements, 2.1 14 Asbestos (CTFA/J4-1 and TM7024)." 15 Do you see that, sir? 16 A. I do. 17 Q. Okay. We know J4-1. 18 What is TM7024 refer to? 19 A. I believe that there's a -- there 20 was another policy that had to do with 21 transmission microscopy also in place. 22 Q. Okay. Well, what do you know, sir, 23 about J&amp;J's testing methods for the presence of 24 talc over time? 25 MS. O'DELL: Object to the form.</p>	<p style="text-align: right;">Page 157</p> <p>1 fold this for a second? 2 I apologize I can't seem to find 3 that. It should be -- you know, there's a 4 Rio Tinto slide deck. It gives a very 5 good chronology. I'll get it in a second, 6 Mr. Ewald. 7 But when TEM really entered into 8 the picture, I found it to be pretty 9 informative because it was -- it's -- it's 10 a little complex exactly what was used by 11 J&amp;J at what points in time. There's a -- 12 there's a good summary of it, and it's in 13 one of the Rio Tinto presentations if 14 somebody will pull up for me once I get 15 it. 16 BY MR. EWALD: 17 Q. All right. Well, we'll get back to 18 that part. 19 My question -- so I have some more 20 questions on J&amp;J testing. 21 But suffice it to say, sitting here 22 right now, you can't tell me what TM7024 is? 23 A. No. And again, I mean, it was a -- 24 it was a -- it was a protocol for transmission 25 electron microscopy.</p>



<p style="text-align: right;">Page 158</p> <p>1 Q. So under --</p> <p>2 A. What's not clear to me exactly from</p> <p>3 the record exactly when J&amp;J used it. Okay. I</p> <p>4 mean, it was not in use. I mean, certainly for</p> <p>5 the -- well, 50 years of this. The use became</p> <p>6 more common in the late '80s and '90s and was</p> <p>7 not -- was not consistently used from what I</p> <p>8 can deduce certainly over the 50-year period.</p> <p>9 It's also not clear to me exactly</p> <p>10 what was done by J&amp;J and J&amp;J inside versus what</p> <p>11 J&amp;J contracted out, I mean, over the 50 years</p> <p>12 as far as transmission electron microscopy.</p> <p>13 Q. Do you have an understanding</p> <p>14 through your research as to which external labs</p> <p>15 were considered amongst the best labs for the</p> <p>16 analysis by microscope of materials for the</p> <p>17 presence of asbestos?</p> <p>18 A. I -- I don't -- I have no opinion</p> <p>19 on what is the best laboratory that J&amp;J used</p> <p>20 over time. You know, we certainly see three</p> <p>21 laboratories involved I believe in the</p> <p>22 2018-2019. I have no opinion on what the best</p> <p>23 laboratory was.</p> <p>24 Q. Okay. So going back to this --</p> <p>25 A. There are --</p>	<p style="text-align: right;">Page 160</p> <p>1 Q. Okay. So does this look familiar</p> <p>2 to you, CTFA method, J4-1, asbestiform,</p> <p>3 amphibole minerals, and cosmetic talc?</p> <p>4 A. Yeah. Can we just put it -- is</p> <p>5 there a date on this?</p> <p>6 I mean, it has not been -- just</p> <p>7 scroll -- scroll back up for a second. Please.</p> <p>8 Q. Issued 10/7/76.</p> <p>9 A. Yeah. That's the date I -- that's</p> <p>10 the date I was just looking for. Yeah.</p> <p>11 Q. All right.</p> <p>12 MR. EWALD: We'll mark this as</p> <p>13 Exhibit 12.</p> <p>14 (Whereupon, Exhibit 12, Document</p> <p>15 entitled, "Asbestiform Amphibole Minerals</p> <p>16 in Cosmetic Talc, Bates labeled</p> <p>17 JNJ 000405219 through JNJ 000405228, was</p> <p>18 marked for identification.)</p> <p>19 MS. O'DELL: Could you kindly put</p> <p>20 it in the chat for us again, please.</p> <p>21 MR. EWALD: Sure. Let me know when</p> <p>22 you have it.</p> <p>23 MS. O'DELL: Okay.</p> <p>24 THE WITNESS: I've got it. I'm</p> <p>25 sorry to make you jump up.</p>
<p style="text-align: right;">Page 159</p> <p>1 Q. Excuse me. What?</p> <p>2 A. I have no -- no opinion of what --</p> <p>3 what -- to rank the J&amp;J contractors.</p> <p>4 Q. All right. So Exhibit 11, we're</p> <p>5 back to that. And next to asbestos (CTFA J4-1)</p> <p>6 (TM7024). You have, "Nondetected. Asbestos is</p> <p>7 defined to be the fibrous</p> <p>8 serpentine, chrysotile and the fibrous forms of</p> <p>9 the amphibole group as represented by amosite,</p> <p>10 anthophyllite, crocidolite, tremolite and</p> <p>11 actinolite."</p> <p>12 Did I read that correctly?</p> <p>13 A. You did, sir.</p> <p>14 Q. And that is the part -- it's</p> <p>15 something similar you quote in 79.1, correct?</p> <p>16 A. Yes, sir. And that definition, if</p> <p>17 you go back, I actually remember searching that</p> <p>18 definition. I mean, that -- that paragraph is</p> <p>19 used over decades by J&amp;J in -- in documents</p> <p>20 like this.</p> <p>21 Q. Now, one of the tests procedures</p> <p>22 that was identified there is J4-1.</p> <p>23 Have you ever looked at the J4-1</p> <p>24 testing procedure?</p> <p>25 A. In detail, sir.</p>	<p style="text-align: right;">Page 161</p> <p>1 MS. O'DELL: You've already</p> <p>2 clicked, so if you do save -- yeah. And</p> <p>3 then open up the -- it should be in the</p> <p>4 folder over there. Yeah. Right there.</p> <p>5 THE WITNESS: It's opening up.</p> <p>6 Thank you, sir. Give me a second. I have</p> <p>7 it in front of me. Let me enlarge, if I</p> <p>8 may, zoom, edit, zoom, view plus.</p> <p>9 I'm almost there, sir. It's just</p> <p>10 going to a different -- I just have to</p> <p>11 make it a little larger. Is there a plus</p> <p>12 sign?</p> <p>13 Zoom to -- hold on a second -- to</p> <p>14 page -- let's go to 100 percent,</p> <p>15 125 percent.</p> <p>16 Thank you, sir. Thanks for letting</p> <p>17 me see it.</p> <p>18 BY MR. EWALD:</p> <p>19 Q. Sure.</p> <p>20 A. I have it in front of me, and</p> <p>21 that's a little too big; but that's okay.</p> <p>22 Q. All right. There's not much to ask</p> <p>23 of this one other than you would agree with me,</p> <p>24 Dr. Kessler, that the title of the method is</p> <p>25 "Asbestiform Amphibole Minerals in Cosmetic</p>

<p style="text-align: right;">Page 162</p> <p>1 Talc," correct?</p> <p>2 A. You know how to read.</p> <p>3 Q. Okay. And if you go to --</p> <p>4 A. The specifications? Yep.</p> <p>5 Q. And examine the ample -- the sample</p> <p>6 for asbestiform fibrous amphibole minerals,</p> <p>7 right?</p> <p>8 It doesn't just say, examine the</p> <p>9 sample for fibrous amphibole minerals, right?</p> <p>10 A. No. Let me just get mine to the</p> <p>11 right size. Give me a second. I expanded it</p> <p>12 so it's more than a hundred percent. So let's</p> <p>13 get it.</p> <p>14 No. I think it's a more -- I think</p> <p>15 that -- the way you phrased it, I would ask you</p> <p>16 to clarify -- I mean, to be a little more</p> <p>17 specific.</p> <p>18 What page are we on?</p> <p>19 Q. Well, we're on page 9 out of 10.</p> <p>20 A. Hold on a second. Let me get</p> <p>21 there. I'm getting there.</p> <p>22 My -- my point exactly here. There</p> <p>23 could not be a better example of what we've</p> <p>24 been talking about over -- since the break.</p> <p>25 Q. Okay. My question was: The title</p>	<p style="text-align: right;">Page 164</p> <p>1 I mean, a test at 14 percent -- a</p> <p>2 sensitivity of 14 percent, you increase the</p> <p>3 specificity here with great individual</p> <p>4 variability, right.</p> <p>5 And, again, as you pointed out, and</p> <p>6 it was good to import to convince FDA this was</p> <p>7 the test for the safety of asbestos when you</p> <p>8 leave out this whole world the chrysotile,</p> <p>9 right. Sort of this -- that is the biggest</p> <p>10 head-scratcher, right.</p> <p>11 How do you convince FDA or the</p> <p>12 world to go along with a test that doesn't even</p> <p>13 test for chrysotile and yet you're putting in</p> <p>14 place a test that has sensitivity that is 14 --</p> <p>15 I mean, 14 percent by the one validation test</p> <p>16 that I saw.</p> <p>17 Q. And what validation -- 14 percent,</p> <p>18 I don't -- I don't see that in your report.</p> <p>19 Maybe I missed it.</p> <p>20 Is it in your report?</p> <p>21 A. Yeah. I mean, it's right there. I</p> <p>22 mean, it's -- you know, it's -- I mean, I</p> <p>23 taught it last -- you know, I -- I teach this</p> <p>24 sensitivity and specificity. Just look at the</p> <p>25 round-robin in '77. I think that was done on</p>
<p style="text-align: right;">Page 163</p> <p>1 for this section is example -- "Examine the</p> <p>2 Sample for Asbestiform Fibrous Amphibole</p> <p>3 Minerals," correct?</p> <p>4 A. Correct.</p> <p>5 Q. And it doesn't just say, examine</p> <p>6 the sample for fibrous amphibole minerals; it</p> <p>7 doesn't say that, correct?</p> <p>8 A. You're missing what the import of</p> <p>9 this section is. You're focusing on a word,</p> <p>10 right; but you're given instructions on</p> <p>11 five character- -- you can ask your question,</p> <p>12 but here is the point.</p> <p>13 They are adding certain specific</p> <p>14 characteristics to meet a definition of</p> <p>15 asbestiform, right. So these are five things</p> <p>16 you have to look at to meet their</p> <p>17 characteristics of a positive test, right.</p> <p>18 So they are -- by doing this, the</p> <p>19 geologists and others are increasing the</p> <p>20 specificity of the test, right. And this is</p> <p>21 why you, in part, right, not the only reason,</p> <p>22 but why you ended up with a sensitivity when</p> <p>23 you tested it ultimately the year after of</p> <p>24 14 percent. This was absolutely useless,</p> <p>25 right.</p>	<p style="text-align: right;">Page 165</p> <p>1 J4-T when they spiked it, and you had one --</p> <p>2 one lab identify it; and six did not. And just</p> <p>3 do the math, and you'll see that in the</p> <p>4 definition of laboratory tests, when six miss</p> <p>5 it and one gets it in the spike sample, that's</p> <p>6 a sensitivity of 14 percent. The test is</p> <p>7 useless.</p> <p>8 Q. Can you tell me again what</p> <p>9 expertise you have to render an opinion that a</p> <p>10 microscopy test for the presence of asbestos is</p> <p>11 not reliable?</p> <p>12 A. Sir, I'm a professor of</p> <p>13 epidemiology and biostat. I mean, basics in</p> <p>14 there -- as I taught medical students a lot</p> <p>15 about sensitivity and specificity of different</p> <p>16 kinds of tests, right.</p> <p>17 When -- when you look at a</p> <p>18 validation study as you do in that '77</p> <p>19 round-robin and you see how many positives and</p> <p>20 negatives you get, it's very easy to do, very</p> <p>21 simple math, right. One out of seven that got</p> <p>22 it is 14 percent, and a 14-percent sensitivity,</p> <p>23 right, no one's going to rely on that; yet, we</p> <p>24 ended up relying on that for decades.</p> <p>25 I mean, this was all a way -- how</p>

<p style="text-align: right;">Page 166</p> <p>1 could you rely on a test that has a sensitivity</p> <p>2 of 14 percent to protect the American public?</p> <p>3 How could you rely on a test,</p> <p>4 right --</p> <p>5 Q. There's no question pending.</p> <p>6 A. But --</p> <p>7 Q. There's no question pending.</p> <p>8 MS. O'DELL: He's not finished.</p> <p>9 THE WITNESS: How do you rely on a</p> <p>10 test, right, that doesn't test for</p> <p>11 chrysotile, right?</p> <p>12 How do you -- how do you -- how do</p> <p>13 you even convince an agency, right, that</p> <p>14 you're giving -- you're giving the</p> <p>15 American publish assurance with this J4-1</p> <p>16 that doesn't test for chrysotile when you</p> <p>17 know there's chrysotile in your product;</p> <p>18 and yet, you say that chrysotile is not an</p> <p>19 issue.</p> <p>20 BY MR. EWALD:</p> <p>21 Q. Are you done, Doctor?</p> <p>22 A. I am -- no. I -- what you're</p> <p>23 hearing from me, right, is -- you want to put</p> <p>24 up J4-1?</p> <p>25 You should know the limitations of</p>	<p style="text-align: right;">Page 168</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Okay. I agree with that. Two</p> <p>3 things, though.</p> <p>4 MR. EWALD: If counsel can please</p> <p>5 tell me what Bates number it is so I can</p> <p>6 have what you're looking at when we come</p> <p>7 back from the break.</p> <p>8 It's also a good time for Suzanne,</p> <p>9 I think, to at least get a glimpse of the</p> <p>10 eclipse, right? Suzanne, no?</p> <p>11 THE COURT REPORTER: It will be in,</p> <p>12 like, another half hour.</p> <p>13 (Discussion held off the record.)</p> <p>14 THE WITNESS: Do you want to go to</p> <p>15 another subject.</p> <p>16 MS. O'DELL: That's fine. And then</p> <p>17 we'll have the document in just a moment,</p> <p>18 and then I'll be happy to give you the</p> <p>19 Bates number.</p> <p>20 THE WITNESS: You will put in the</p> <p>21 chat.</p> <p>22 MS. O'DELL: Yeah. We'll put it in</p> <p>23 the chat as well.</p> <p>24 MR. EWALD: Perfect.</p> <p>25</p>
<p style="text-align: right;">Page 167</p> <p>1 J4-1, right, and you should know what the</p> <p>2 sensitivity is; and you should know that it did</p> <p>3 not protect the American public. I am not</p> <p>4 done.</p> <p>5 Q. Okay. Let's look -- so there's</p> <p>6 some discussion that you feel like, you know,</p> <p>7 maybe there's some J&amp;J TM work in the late</p> <p>8 '80s, '90. You're not really sure.</p> <p>9 And so I'm going to show you some</p> <p>10 documents. Maybe you've seen them before.</p> <p>11 A. That's not -- that's not what I</p> <p>12 said.</p> <p>13 MS. O'DELL: Object to the form.</p> <p>14 THE WITNESS: Okay. That's not</p> <p>15 what I said.</p> <p>16 What -- what's represented by your</p> <p>17 companies and its contractors, if you look</p> <p>18 at the testing history, okay, and there</p> <p>19 are documents; and you can just see, there</p> <p>20 are -- Rio Tinto, if I can just get that.</p> <p>21 It's printing.</p> <p>22 Why don't we just take a break for</p> <p>23 a second, and let me just get this</p> <p>24 document in front of me so the record can</p> <p>25 be clear so I have it in front of us.</p>	<p style="text-align: right;">Page 169</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Let's talk about geology. And</p> <p>3 actually, is the -- if you go to paragraph 80.</p> <p>4 A. Yes.</p> <p>5 Q. Is that the Rio Tinto one you're</p> <p>6 referring to or something else?</p> <p>7 A. No. There's a -- there's a lot of</p> <p>8 Rio Tinto. There are a number of different</p> <p>9 versions of that. In fact, I think there's a</p> <p>10 number of Julie Pier slide decks. So we have</p> <p>11 to find exactly.</p> <p>12 Q. Right.</p> <p>13 A. But the one at TEM is from a Julie</p> <p>14 Tinto [sic] -- I apologize -- Julie Pier Rio</p> <p>15 Tinto slides. You are correct.</p> <p>16 Q. So on geology you cite a number of</p> <p>17 pages of what goes in and then a variety of the</p> <p>18 other sources.</p> <p>19 How did you go about reviewing the</p> <p>20 geological issues associated with talc and</p> <p>21 asbestos?</p> <p>22 A. So there were a number of meetings,</p> <p>23 including the IWGACP. There were other</p> <p>24 meetings that FDA held where they had</p> <p>25 geologists come and present.</p>

<p style="text-align: right;">Page 170</p> <p>1 I mean, this is the, you know, the  2 unique thing about FDA. FDA finds itself  3 regulating substances that intersect with  4 environmental, geological, mineralogical  5 substances all the time. You know, whether  6 it's lead, I mean, other -- other issues in  7 their products.  8 So the FDA would bring in the  9 geologists that there were a number of  10 geologists that I cite that were from FDA  11 presentations. So I looked at that.  12 I also went -- I wanted to see -- I  13 pulled the Laura Webb, who I believe is the  14 defendant expert witness. I went to see -- to  15 read her comments in response to the IWGACP  16 working group. She filed comments. I went to  17 read her expert report in part.  18 So I was interested in looking at  19 this the way FDA would look at this and have to  20 educate themselves from a geological point of  21 view. Again, not substituting myself for the  22 geology experts; but again, on that interface  23 when, as FDA did in this matter, to bring in  24 the geologists to understand the interface  25 between it's regulated products and the</p>	<p style="text-align: right;">Page 172</p> <p>1 it's the starting place of what to expect, I  2 mean, in the -- in this material. Again, I  3 think that there is very little data if you  4 look at the -- the record here that the Vermont  5 mines -- again, I think probably what's being  6 printed -- we have that -- we'll show the  7 possibility of serpentine materials certainly  8 in those mines were to be anticipated.  9 And my only point is that the  10 safety, you know, that there's some debate  11 here, and I go in to it; but, you know, it's  12 not been established. So there's uncertainty,  13 and I recognize that; and I'm trying to  14 recognize the complexities that are associated  15 when you start with the geology and then  16 translate that into the mineralogy and then  17 into the epidemiology. And no one has anyway  18 cleared the non-asbestiform fibers to  19 substantiate the safety in my opinion.  20 Q. So in 83.15 you're -- are you  21 suggesting that Dr. Van Gosen disagrees with  22 Dr. Webb, that one must, in fact, understand  23 the details of the local and regional geology  24 of any given mine, including the potential for  25 complex distribution of rocks at different</p>
<p style="text-align: right;">Page 171</p> <p>1 potentially hazardous products that are  2 geologically or mineralogically derived.  3 Q. Okay. So for example, with your  4 discussion of Laura Webb, 83.15, page 26. Let  5 me know when you're there.  6 A. Hold on a second 83 point --  7 Q. 15.  8 A. Right.  9 Q. Are you there?  10 A. I am, sir.  11 Q. Okay. I couldn't understand what  12 you said. So what is -- what does Laura Webb's  13 opinions that you're excerpting there impact  14 have on your opinions here?  15 A. Yeah. So this is all under the  16 conclusion here. I mean, if you go to the --  17 to the section of this, I mean, as you know,  18 Dr. Van Gosen came to an FDA public meeting;  19 and he took -- he took -- he took FDA through  20 the interrelationship that drives from the  21 geological environment of talc. And, for  22 example, he did it on the anthophyllite forms  23 and how those were related. Dr. Webb agrees in  24 part, disagrees in part with Dr. Van Gosen.  25 And what you can see is, again,</p>	<p style="text-align: right;">Page 173</p> <p>1 metamorphic grades resulting from complex  2 tectonic history?  3 MS. O'DELL: Object to the form.  4 THE WITNESS: That's not  5 Dr. Van Gosen. That's Dr. Webb if I'm  6 correct.  7 BY MR. EWALD:  8 Q. Do you think that -- is it your  9 opinion that Dr. Webb disagrees with -- sorry.  10 Is it your opinion that  11 Dr. Van Gosen disagrees with that quote from  12 Dr. Webb?  13 A. I'm not saying she does -- he does.  14 I'm not -- I'm not saying there is a  15 disagreement there. I mean, I -- I put it in  16 there because I think, one -- I mean, I think  17 that is the view of the geologists. I think  18 that one has to take that into account.  19 And I mean, there are  20 certain things -- there -- you know, there are  21 certain categories that geologists, they -- the  22 people who are involved for 50 years expected  23 certain type of geological formations gave  24 potential for certain risks. But knowing the  25 local characteristics, I mean, is certainly</p>

<p style="text-align: right;">Page 174</p> <p>1 something that was for important for the 2 totality of evidence here. 3 Q. Well, you have on your materials 4 considered list an expert report, MDL from 5 Dr. Mary Poulton. 6 Did you review that expert report? 7 A. I would have to -- I would want to 8 review -- I'd want to review that and pull that 9 in front of me. 10 Q. Have you -- sitting here today, do 11 you recall reviewing the report of Dr. Mary 12 Poulton? 13 A. I'd have to go back. I'm drawing a 14 blank for the moment. 15 Q. What are you relying on, if 16 anything, for your understanding of J&amp;J's 17 mining practices over the years? 18 A. So there is -- I mean, there's a 19 rich history of Bill Ashton. There is a -- I 20 mean, there are documents that -- let me -- 21 THE WITNESS: Do you have my pie 22 chart? 23 I just -- I need my pie chart. 24 (Discussion held off the record.) 25 THE WITNESS: I'm still told it's</p>	<p style="text-align: right;">Page 176</p> <p>1 So for example, there's a pie chart 2 of Rio Tinto mineral slide deck talc deposit 3 mineralization by world production, and they 4 divide this up by world production; and they 5 employ the same pathway formation of talc. And 6 they do 20 percent of the world production is 7 Serpentine Host Rock and RTM Vermont, and it 8 says potential for serpentine asbestos. And 9 there are certain versions of this pie chart 10 that have a footnote that say that the -- 11 exactly what's in that quote, that you should 12 suspect the possibility based on local 13 characteristics. 14 So I mean -- 15 MS. O'DELL: John, just for 16 verification purposes, this is an IMERY'S 17 PowerPoint. It's analytical capabilities 18 to test methods dated June 2009, and I'll 19 give the Bates number to you shortly. 20 THE WITNESS: And then there is 21 also -- I owe Mr. Ewald a discussion of 22 the history of TEM, and there is that 23 slide too. If you can just help me find 24 this slide deck. There's a -- it's one of 25 the Rio Tinto slides.</p>
<p style="text-align: right;">Page 175</p> <p>1 being printed. This is the famous 2 document that's being printed. 3 I just need -- there's a pie chart 4 here, and there's a TEM chart. And, 5 again, I apologize. As soon as that's -- 6 I'm just looking to look for it. 7 BY MR. EWALD: 8 Q. While you're looking for -- 9 A. I mean, there's -- there's -- do 10 you want to -- can I just give you the -- 11 thanks. I just want to pull that in front of 12 me. 13 Q. I'm sorry. What are you doing now, 14 sir? 15 A. I'm just looking at the materials 16 in front of me for -- here we go. And there's 17 another version of this. There are two 18 versions of this. There's two versions of 19 this. Yeah. Can you just pull up -- let's 20 start with the pie chart there. Just give me 21 one second. 22 And there's some different 23 footnotes on these different pages, and there 24 is another pie chart. Yeah. There's a 25 different pie chart.</p>	<p style="text-align: right;">Page 177</p> <p>1 Yeah. It's -- there's a Julie -- 2 exactly. 3 Sorry, Mr. Ewald. We'll get those 4 to you. 5 BY MR. EWALD: 6 Q. All right. So -- so let's, while 7 we're waiting for -- I'm not sure we're waiting 8 anymore. 9 MR. EWALD: Jake, can you please 10 drop in the Mary Poulton report. I'll pop 11 it on the screen. 12 THE WITNESS: I do have the 13 footnotes here. Here is one footnote 14 where on -- there's a slide deck, 15 analytical capabilities and test methods 16 June 2009 is talc deposit mineralization 17 by world production. 18 There's a note that says, "All talc 19 deposits have risk of localized asbestos 20 if isolated metamorphic events occur in or 21 near the deposit. 22 MS. O'DELL: And I will -- 23 Dr. Kessler, is this the one you would 24 like to put it in chat. 25 THE WITNESS: Yeah. I mean, I hope</p>



<p style="text-align: right;">Page 178</p> <p>1 that's the -- it's this slide, Mr. Ewald, 2 please. Just make it has the footnote. 3 Some of them don't have the footnote 4 that -- I think that footnote 5 characterizes it pretty well. 6 MS. O'DELL: Okay. 7 BY MR. EWALD: 8 Q. Okay. While we're putting that in 9 the chat, I put it in -- Jake put in the report 10 of Mary Poulton. I am not going to ask about 11 it in depth, but I do want you to have a chance 12 to take a look at it just to see if it's 13 something that you ended up reviewing. 14 MS. O'DELL: Just click it out of 15 the chat. 16 THE WITNESS: This is 2019-02. Is 17 that the document I'm doing? 18 BY MR. EWALD: 19 Q. Yes. 20 A. Thank you very much. 21 General causation -- one second. 22 Yeah. This is a response, I guess, to Cook and 23 Krekeler. I'm not going to pronounce it right. 24 It's a response to them. 25 I don't have a -- I don't know</p>	<p style="text-align: right;">Page 180</p> <p>1 others. I think that the notion of 2 quality control in China is a very big 3 complex issue, right. 4 She -- I mean, she's talking about 5 I am sure -- you know, I have no opinions 6 on -- between her and Cook. I mean, there 7 are other -- on -- you know, they can 8 discuss the Vermont mines. 9 I think where -- I think we would 10 all agree that complex -- the quality 11 control in China -- and I -- I've tried to 12 look at those documents. You know, 13 anything about quality control in China, I 14 think I -- I would -- I see she doesn't 15 get into that in any real significant way 16 if I remember because I was looking for 17 that. 18 You see there's one paragraph on 19 China, right. But to say -- to talk about 20 the quality control and selective mining, 21 you know, I don't think anyone is -- and I 22 tried to go back and look at those audits 23 and actual visits to China; and I think 24 there's -- there's great unknowns on the 25 quality there.</p>
<p style="text-align: right;">Page 179</p> <p>1 whether I -- I don't know -- I don't remember 2 studying it the same way that I studied Webb. 3 Q. Okay. And -- 4 A. This response to Cook, right? 5 Q. Right. And to the extent that 6 Dr. Poulton makes certain opinions regarding 7 selective mining, the ability of J&amp;J to avoid 8 areas that may contain asbestos, you don't have 9 the expertise to disagree with her, correct? 10 MS. O'DELL: Object to the form. 11 THE WITNESS: I'm -- I'm not going 12 to -- you know, I'm not being going to -- 13 just give me one second. Let me just -- 14 let me just study this a little please. 15 Thank you. 16 Yeah. So she's focusing, if I'm 17 correct, how drill campaigns -- on drill 18 campaigns, mine planning, and how 19 effective the quality control is, right. 20 You know, I do -- I do want to put 21 on the -- well, let me just see something. 22 Let me just look at this. 23 Yeah. So let me just point out 24 what -- I think -- I mean, I have studied 25 this issue a little. I leave it to</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. EWALD: 2 Q. When you say "great unknowns," 3 you're talking about any experience you might 4 have had in other areas relating to China, and 5 you haven't had any specific evidence about a 6 lack of quality control as it relates to China 7 top mines -- 8 MS. O'DELL: Object to the form. 9 THE WITNESS: Yeah. So I -- so I 10 do have -- I mean, if you do look at the 11 amount of quality control data that is in 12 the administrative record on China, it 13 is -- I mean, I -- I was not -- there -- 14 there is not a lot. 15 If you look at the total number of 16 samples that were tested in China in the 17 record over the years that J&amp;J has put -- 18 I mean, I think there's -- there's very 19 significant questions about the oversight 20 in China. And I -- and I see she cites 21 that stuff. 22 BY MR. EWALD: 23 Q. Right. On the -- if you could 24 please turn -- 25 A. I just need one second to clean up</p>

<p style="text-align: right;">Page 182</p> <p>1 here so I can --</p> <p>2 Q. Sure.</p> <p>3 A. -- keep track of the documents.</p> <p>4 Thank you so much.</p> <p>5 Q. Sure.</p> <p>6 A. And I still need that TEM document.</p> <p>7 Q. I'm not going there yet. We'll do</p> <p>8 that on the break.</p> <p>9 A. Thank you very much. Thanks for</p> <p>10 waiting.</p> <p>11 Q. So turn, please, to the</p> <p>12 Subsection A that starts on page 46.</p> <p>13 A. Yes.</p> <p>14 Q. All right. And you --</p> <p>15 THE WITNESS: Can I just trouble</p> <p>16 you. Can you hand me my lab binders -- my</p> <p>17 lab test binders, please?</p> <p>18 MS. O'DELL: Yep.</p> <p>19 THE WITNESS: Just one second. Let</p> <p>20 me just get my binder in front of me so I</p> <p>21 don't have to jump up and down.</p> <p>22 Thank you very much, sir. I'm</p> <p>23 happy to discuss anything.</p> <p>24 BY MR. EWALD:</p> <p>25 Q. Sure. You mentioned earlier in the</p>	<p style="text-align: right;">Page 184</p> <p>1 is in paragraph 114. Did you ask -- actually,</p> <p>2 115. Sorry.</p> <p>3 Did you ask plaintiff's counsel,</p> <p>4 hey, do you know if there are any other</p> <p>5 documents other than what I'm citing here</p> <p>6 relating to that historical back-and-forth?</p> <p>7 A. Yes.</p> <p>8 Q. Okay.</p> <p>9 THE WITNESS: Can I have my</p> <p>10 Hutchinson binder please?</p> <p>11 That is a good example, and it's</p> <p>12 worth pointing out, yes. I was very</p> <p>13 interested in that because that went to</p> <p>14 the -- I -- I have a document. I</p> <p>15 specifically asked for that because I was</p> <p>16 trying to sort out the Dr. Lewin issues.</p> <p>17 BY MR. EWALD:</p> <p>18 Q. Okay. And so what was your</p> <p>19 thinking in setting out in your report that</p> <p>20 discussion where you only discussed part of the</p> <p>21 story in paragraph 115, fair?</p> <p>22 A. Which paragraph, sir?</p> <p>23 Q. 115.</p> <p>24 MS. O'DELL: Excuse me. Let me</p> <p>25 make sure my objection is noted.</p>
<p style="text-align: right;">Page 183</p> <p>1 day that, to the extent possible, it was</p> <p>2 important for you to get a complete story on</p> <p>3 issues that you're talking about in the report,</p> <p>4 fair?</p> <p>5 A. That's a general -- general subject</p> <p>6 of aspiration. I implored you, right. I try</p> <p>7 to get as complete.</p> <p>8 Q. And you talked a little bit about</p> <p>9 the steps you took to do that. At any point in</p> <p>10 time did, when you were talking about some of</p> <p>11 the incidents discussed starting on, let's say,</p> <p>12 110, footnotes and ensuing paragraphs, asked</p> <p>13 counsel if there were other documents that you</p> <p>14 haven't identified that spoke to those</p> <p>15 particular issues?</p> <p>16 MS. O'DELL: Object to the form.</p> <p>17 THE WITNESS: So whether there were</p> <p>18 laboratory tests, we're talking about in</p> <p>19 the sphere of testing; is that correct?</p> <p>20 I just want to get the scope if</p> <p>21 that's this section.</p> <p>22 BY MR. EWALD:</p> <p>23 Q. Yeah. Right. For example, you --</p> <p>24 let me give you an example. Sorry.</p> <p>25 You reference the Hutchinson, which</p>	<p style="text-align: right;">Page 185</p> <p>1 Object to the form of the question.</p> <p>2 THE WITNESS: I'm -- you know,</p> <p>3 again, as this is the life I learned --</p> <p>4 lead -- we all lead, right -- that I have</p> <p>5 when I'm writing books is how much do you</p> <p>6 put in and how much -- I can go into -- I</p> <p>7 can write a report, and I have a -- I have</p> <p>8 a binder that, you know, assembled that</p> <p>9 has, you know, a reliance list.</p> <p>10 I must have -- I don't know -- 20</p> <p>11 documents or so that go into exquisite</p> <p>12 detail exactly when Hutchinson at the</p> <p>13 airport ends the reports the day before</p> <p>14 they go into FDA. And say there's no</p> <p>15 chrysotile when he says there's</p> <p>16 chrysotile.</p> <p>17 I can go into that story in</p> <p>18 exquisite detail. The documents should be</p> <p>19 on my reliance list. The question is how</p> <p>20 much -- whatever you'd like to discuss. I</p> <p>21 mean, I think -- I think it is an</p> <p>22 important story.</p> <p>23 BY MR. EWALD:</p> <p>24 Q. Well, I guess one question is in</p> <p>25 reviewing some of the documents that you</p>

<p style="text-align: right;">Page 186</p> <p>1 suggest that you have, does that impact your</p> <p>2 assessment of the reliability of the results</p> <p>3 that were initially reported and discussed</p> <p>4 on -- in paragraph 115?</p> <p>5 MS. O'DELL: Objection. Vague.</p> <p>6 THE WITNESS: Let me just -- let me</p> <p>7 just read all of 115. Give me one second</p> <p>8 to review 115, and then I will tell you</p> <p>9 the impacts. I just need a second to</p> <p>10 review this.</p> <p>11 I mean, I've been focused on the...</p> <p>12 This is Figure 17A and 18A. Yeah.</p> <p>13 So yeah. I see that paragraph.</p> <p>14 Ask your question again, sir, please.</p> <p>15 BY MR. EWALD:</p> <p>16 Q. Well, so, for example, are you</p> <p>17 aware that McCrone tested the same sample by</p> <p>18 TEM and did not find any chrysotile?</p> <p>19 A. Sir, I can tell you in -- let's --</p> <p>20 give me one second. Give me one second.</p> <p>21 So I'm aware that there are a lot</p> <p>22 of people who testify -- there was Sperry Rand,</p> <p>23 who did find -- I have a -- in this -- it</p> <p>24 should be -- I have a handwritten chronology.</p> <p>25 It must be -- did it fall out?</p>	<p style="text-align: right;">Page 188</p> <p>1 Q. Well, do you have any expertise as</p> <p>2 to be able to decide whether, for example,</p> <p>3 Dr. Hutchinson just got it wrong?</p> <p>4 MS. O'DELL: Object to the form.</p> <p>5 THE WITNESS: I have every</p> <p>6 expertise in the world to know the answer</p> <p>7 to the question is: Do you have any shred</p> <p>8 of evidence, right.</p> <p>9 And, I mean, I think most people</p> <p>10 would -- would agree that he may have --</p> <p>11 you can decide, you know, exactly -- you</p> <p>12 can be the arbitrator, who's right, who's</p> <p>13 wrong.</p> <p>14 But the answer to the question,</p> <p>15 okay, that -- let's just look -- if you</p> <p>16 look on at 11/1/72, right, there isn't a</p> <p>17 shred of evidence, right, that there's</p> <p>18 asbestos in Shower to Shower.</p> <p>19 When you have that Hutchinson</p> <p>20 come -- on, Mr. Ewald. You don't</p> <p>21 disagree. You -- there's a shred --</p> <p>22 there's not only a shred of evidence.</p> <p>23 There was -- you could sit there, please,</p> <p>24 I mean --</p> <p>25</p>
<p style="text-align: right;">Page 187</p> <p>1 I have a handwritten chronology.</p> <p>2 Sperry Rand did find it. And so, you know,</p> <p>3 again -- here it is. I'm sorry. Thank you.</p> <p>4 This is my notes. And so I can</p> <p>5 tell you on -- on what date would you -- what</p> <p>6 date are you referring to of McCrone because I</p> <p>7 can -- we can look at those documents? I'm</p> <p>8 happy to pull those up for you or with you.</p> <p>9 We can look at what McCrone found.</p> <p>10 We can look at what Sperry Rand found. We can</p> <p>11 look at what Dr. Hutchinson found.</p> <p>12 But the fact is Hutchinson found</p> <p>13 this, right. Made sure J&amp;J knew about this.</p> <p>14 J&amp;J walk in and say, no shred of evidence.</p> <p>15 So it may be that McCrone found,</p> <p>16 you know, McCrone found what, you know, what</p> <p>17 McCrone found. But if you're going to tell FDA</p> <p>18 that there's no shred of evidence and they had</p> <p>19 in their possession what Hutchinson said is</p> <p>20 incontrovertible evidence, right, of</p> <p>21 chrysotile, you know, you can draw whatever</p> <p>22 conclusions you want. I don't get that. I</p> <p>23 don't get that, how that happens. I don't get</p> <p>24 how the general would allow that to happen in</p> <p>25 his company.</p>	<p style="text-align: right;">Page 189</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Listen, I'm not -- I'm not going to</p> <p>3 tell you what you believe. Don't tell me what</p> <p>4 I believe.</p> <p>5 A. I'm not.</p> <p>6 Q. You just did.</p> <p>7 A. I'm telling you --</p> <p>8 Q. You just did.</p> <p>9 A. But I'm telling you that -- I'm</p> <p>10 telling you the history is not very good for</p> <p>11 your client.</p> <p>12 Q. Okay. And --</p> <p>13 MS. O'DELL: John, excuse me.</p> <p>14 We're -- we're at 2:26. I think we agreed</p> <p>15 to take a break for Suzanne. I think she</p> <p>16 was looking at being able to get up and</p> <p>17 outside by 2:30.</p> <p>18 So is this a good time for a break?</p> <p>19 MR. EWALD: Why not?</p> <p>20 MS. O'DELL: Okay. We are off the</p> <p>21 record.</p> <p>22 THE COURT REPORTER: Okay. We're</p> <p>23 off the record.</p> <p>24 (Whereupon, a break was taken.)</p> <p>25</p>

<p style="text-align: right;">Page 190</p> <p>1 BY MR. EWALD:</p> <p>2 Q. All right. Doctor, off the top,</p> <p>3 we'll go back to the topic we left off later.</p> <p>4 I want to talk about your Section 5, amongst</p> <p>5 other things, which starts on page 58.</p> <p>6 A. Yeah. Can I turn to my epi</p> <p>7 binders?</p> <p>8 Yes, sir.</p> <p>9 Q. And in particular, I want to start</p> <p>10 with your concluding paragraph on 154. It's</p> <p>11 the end of that section on page 67.</p> <p>12 A. 157?</p> <p>13 Q. 154 on page 67.</p> <p>14 A. Thank you, sir. Give me a second.</p> <p>15 Q. Of course.</p> <p>16 A. Yes, sir.</p> <p>17 Q. Okay. And so in this concluding</p> <p>18 paragraph, you identify three things that</p> <p>19 supports your conclusion that plaintiffs failed</p> <p>20 to substantiate the safety of its talcum powder</p> <p>21 products.</p> <p>22 First, is the FDA's 2014 petition</p> <p>23 response acknowledging that there remains some</p> <p>24 evidence to suspect or question the safety of</p> <p>25 talcum powder products. And on that I will</p>	<p style="text-align: right;">Page 192</p> <p>1 Which one are you -- when you're</p> <p>2 pointing out these paragraphs?</p> <p>3 Q. I'm going by specific paragraph</p> <p>4 number. I started out by focusing on the FDA</p> <p>5 2014 petition response. In particular, I noted</p> <p>6 145 where the FDA responds -- or you quote from</p> <p>7 it where it notes that it is plausible that</p> <p>8 perineal talc has a particulate that reaches</p> <p>9 the endometrial cavity, right?</p> <p>10 A. Yeah. That is -- that is -- that</p> <p>11 is part of the FDA response that acknowledges</p> <p>12 that there are -- there's some evidence to</p> <p>13 suspect a question of safety of talc products.</p> <p>14 Q. Okay.</p> <p>15 A. The FDA uses that. I mean, it's</p> <p>16 not that -- I mean, I am -- the reason I'm</p> <p>17 being a little careful, I am not doing -- you</p> <p>18 know, under 154A, FDA is doing that analysis of</p> <p>19 those mechanisms of action, correct?</p> <p>20 Q. Right.</p> <p>21 A. I'm citing simply the fact that FDA</p> <p>22 has said there are -- there's some evidence</p> <p>23 with respect to your question of safety, right,</p> <p>24 in that petition response. And they use that</p> <p>25 as a basis to do that.</p>
<p style="text-align: right;">Page 191</p> <p>1 pause. There are a couple of different</p> <p>2 paragraphs, but you note in paragraph 145 the</p> <p>3 FDA's response noting the biological</p> <p>4 plausibility of talc reaching the endometrial</p> <p>5 cavity, fair?</p> <p>6 A. Yes, I cite that; yes, sir.</p> <p>7 Q. Okay. And then you cite to the</p> <p>8 totality of the medical literature. It says</p> <p>9 2014 that continues to raise safety questions;</p> <p>10 and then within this section overall, you refer</p> <p>11 to a number of such studies, fair?</p> <p>12 A. Yeah. Tell me -- I'm a little</p> <p>13 confused. So you -- we're going back on 2014.</p> <p>14 A is the FDA's petition itself acknowledges --</p> <p>15 Q. Right.</p> <p>16 A. -- that there -- there are some</p> <p>17 evidence. So you're citing some of the</p> <p>18 evidence that they are citing some of the</p> <p>19 evidence, but their review is that there is</p> <p>20 some unanswered questions, right, I mean, about</p> <p>21 this. And you're picking out some of the</p> <p>22 evidence in their response.</p> <p>23 Are you under A, or are you under</p> <p>24 all -- everything in my 154? That's why -- I</p> <p>25 apologize.</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. And then C on 154 refers to IARC's</p> <p>2 classification as talc-based body powder as</p> <p>3 possibly carcinogenic to humans, right?</p> <p>4 A. So can I just have my -- my art?</p> <p>5 What you have is you have both a 2B</p> <p>6 classification, and you have a 1 classification</p> <p>7 for both 2010 and 2012. So you have the 2B,</p> <p>8 and then you have the Group 1 classification of</p> <p>9 all forms of asbestos, right, in 2012. I mean,</p> <p>10 it deals with asbestiform talc and talc with</p> <p>11 asbestos. So you've got Group 1 and 2B for</p> <p>12 IARC.</p> <p>13 Q. Right. And all of the evidence</p> <p>14 that you talk about in Section 5 starting</p> <p>15 around 58 and summarize in that paragraph 154</p> <p>16 conclusion ever since is publicly available</p> <p>17 information, correct.</p> <p>18 A. Yeah.</p> <p>19 Q. Okay. And is it -- do you have a</p> <p>20 view as to when there was enough evidence as to</p> <p>21 defendant's failing to substantiate the safety</p> <p>22 of their talcum powder products?</p> <p>23 A. Yeah.</p> <p>24 Q. What date?</p> <p>25 A. I think if you go back to the</p>

<p style="text-align: right;">Page 194</p> <p>1 original Tenovus finding of -- I mean, I'm not  2 sure I -- well, I give an -- I don't think I  3 give an opinion specifically on that.  4 But in response to your question, I  5 think once you find needles in Tenovus deep in  6 the ovary and they have evidence that their  7 product contained, quote, "the fibers," I think  8 there was -- there was not -- certainly there  9 was -- there was serious questions that were  10 raised that could not substantiate the safety  11 of the product back in the '70s.  12 Q. Do you think from an  13 epidemiological standpoint, that the Cramer  14 1982 study was sufficient to raise enough  15 questions on the safety of talc products?  16 MS. O'DELL: Object --  17 THE WITNESS: I am not basing my  18 last answer on any one epidemiological  19 study. I think, though, that once you  20 have -- again, I mean, failing to -- the  21 obligation was for J&amp;J to substantiate the  22 safety, right.  23 You don't have to prove that -- you  24 don't have to prove the -- you don't need  25 epidemiological statistical significance</p>	<p style="text-align: right;">Page 196</p> <p>1 147 concluding footnotes to 151, do you intend  2 to offer any other opinions regarding that  3 ovarian cancer epidemiology?  4 MS. O'DELL: Object to the form.  5 THE WITNESS: So again, I think you  6 have -- I won't use any adjectives.  7 You -- you have experts who will do  8 the epidemiology, meaning who can talk  9 about recall bias and never use and ever  10 use.  11 I'm happy to, again, as a professor  12 of epidemiology, if you want to ask me any  13 questions; but I leave it to those other  14 experts to talk about epidemiology  15 certainly as it relates to causation,  16 right. I told you I wasn't going to do  17 causation. I'm not going to do causation.  18 Where this epidemiology comes into  19 play, right, I -- you -- you certainly  20 have varying degree of biological  21 evidence, right. You have the animal  22 pathological. You have histological. You  23 have epidemiological evidence. Again, is  24 the interplay between that epidemiology  25 and responsibilities under the act.</p>
<p style="text-align: right;">Page 195</p> <p>1 to raise questions about safety.  2 I think in the '70s you didn't  3 have -- you couldn't substantiate the  4 safety. Once you have Tenovus and once  5 you have fibers, how can you substantiate  6 the safety? It raised enough questions to  7 undermine any substance to say you can  8 ensure the safety of the product.  9 That's not the same thing as, you  10 know, ruling something in, right. I mean,  11 is the epidemiological -- we now know that  12 there's a small statistically significant  13 increased risk, I mean; but that's not the  14 same thing as failing to substantiate the  15 safety.  16 You understand what I'm saying, I  17 hope.  18 BY MR. EWALD:  19 Q. I guess I'm unclear on the  20 epidemiology. You note in 146 that you leave  21 to other experts to discuss in detail the  22 strengths weaknesses and specifics of the  23 scientific evidence.  24 What are you -- beyond what you  25 include in the report about epidemiology from</p>	<p style="text-align: right;">Page 197</p> <p>1 Again, the responsibility here is  2 J&amp;J, as I understand, it has to  3 substantiate the safety of its product,  4 right.  5 Where epidemiology -- the  6 epidemiology cannot be said to  7 substantiate the safety of this product.  8 In fact, the epidemiology, you know,  9 certainly today, I mean, raises questions  10 about it; and it has raised questions for  11 several decades, right.  12 So what I will stay with the  13 opinions that are specifically -- you  14 know, the heading is a good example. And  15 in 154 this is to support the fact that  16 they fail to substantiate the safety of  17 their talcum products. I mean, I rely on  18 what FDA -- rely may be wrong, but I  19 reference what FDA has said.  20 I look at the evidence myself, feel  21 very comfortable, you know, discussing  22 what -- what the epidemiology is and what  23 international bodies and agencies have  24 said.  25 And I take that against the</p>



<p style="text-align: right;">Page 198</p> <p>1 regulatory question: Did they 2 substantiate the safety of the talcum 3 product. 4 And in light of that, epidemiology 5 studies that still -- that show a small 6 significant -- significant increase. 7 Again, epidemiologists can spend their 8 careers discussing dispense and 9 limitations and exactly what all that 10 means. 11 I think there's no doubt in my 12 mind, in light of that record, the 13 defendants failed to substantiate the 14 safety of the product. 15 That's what I would offer. 16 BY MR. EWALD: 17 Q. And when you -- when you say that 18 epidemiology has raised questions going back 19 several decades, how far back in your mind? 20 A. Well, so let me -- hold on one 21 second. 22 So again, I'm not going to give an 23 exact, you know, I mean, opinion; but I think 24 you have certainly studies, you know, as you 25 reference of Cramer in '82, Hartge in '83. You</p>	<p style="text-align: right;">Page 200</p> <p>1 THE WITNESS: So this isn't -- 2 yeah. 3 BY MR. EWALD: 4 Q. Is it your -- I'm sorry. Go ahead. 5 A. I just want to -- I really 6 appreciate the question. I just want to make 7 sure I get it. 8 Has the FDA concluded that -- has 9 FDA concluded that the companies have not 10 substantiated the safety? 11 Is that -- is that -- ever said the 12 companies have not substantiated the safety? 13 Q. Well, that's one question. That's 14 the first one. Go ahead. 15 A. So I don't -- I mean, I think that 16 if you look at the response to the petitions, 17 FDA got side -- sidetracked are two things and 18 did not look at that essential question under 19 the statute, which they should have done. 20 I think they looked at, in response 21 to Sam Epstein's petition, the question was, 22 you know, did they say whether there was 23 definitive evidence to -- whether there was 24 definitive evidence or evidence to definitively 25 say to require a warning.</p>
<p style="text-align: right;">Page 199</p> <p>1 have a whole bunch of case control studies in 2 the '80s that certainly, you know, at the very 3 least, even with their limitations, raise 4 questions about the safety. 5 But I think -- I think you have 6 that -- again, once you find -- once you find 7 needles, I mean as Tenovus in the -- in the 8 deep tissue, I think, you know, you don't need 9 epidemiology if you find the needle and you 10 have that pathology to raise questions. 11 Causation is a different mass. 12 Q. Is it your opinion that at any 13 point in time, the FDA has concluded that 14 cosmetic talc manufacturers like J&amp;J have 15 misbranded labels for not having a warning 16 substantiated? 17 MS. O'DELL: Could you repeat the 18 question? 19 MR. EWALD: Yeah. 20 THE WITNESS: I want to -- I want 21 to study that question. 22 BY MR. EWALD: 23 Q. Sir -- 24 MS. O'DELL: He's just reviewing 25 the question on realtime.</p>	<p style="text-align: right;">Page 201</p> <p>1 That's -- that was not the standard 2 for cosmetics, but that was the standard in the 3 petition; so they were answering the petition, 4 right. But the -- the real question, right, I 5 mean, in front of FDA is, you know, for 6 50 years your company said -- told this agency 7 there's not asbestos in this product, right. 8 And I think that has -- that's 9 been -- that's shaped everything, and the -- 10 the agency, you know, gives great -- put great 11 reliance in what the company said for 50 years 12 that there was no asbestos. 13 So I mean, if there's no asbestos, 14 then there's no issue of substantiating the 15 safety. The FDA was completely misled here. 16 Q. Okay. So your -- it's your opinion 17 that if there is no asbestos determination, 18 that the safety has been substantiated for 19 talcum powder products? 20 A. No. 21 MS. O'DELL: Object to the form. 22 THE WITNESS: You almost got it 23 right. If there is -- if there is no 24 asbestos -- there's going to be two 25 negatives -- too many negatives in this.</p>

<p style="text-align: right;">Page 202</p> <p>1 But if there's no question about</p> <p>2 asbestos -- if you say to the FDA, no --</p> <p>3 we've taken care of the risk, right,</p> <p>4 you're worried about asbestos. Asbestos</p> <p>5 is a human carcinogen. We've taken care</p> <p>6 of the risk. There's no asbestos. We've</p> <p>7 closed down mines. We -- we have a -- we</p> <p>8 have this under control. We've never</p> <p>9 found it. No asbestos. No asbestos. No</p> <p>10 asbestos, right.</p> <p>11 You basically put FDA's mind at</p> <p>12 ease, right, that they don't have to lose</p> <p>13 sleep that this product is causing harm.</p> <p>14 That is different, right, than</p> <p>15 whether your company has substantiated the</p> <p>16 safety. I just believe your company --</p> <p>17 that there was no asbestos here. That was</p> <p>18 the mistake.</p> <p>19 So when Sam Epstein comes in and</p> <p>20 says it requires a definitive warning,</p> <p>21 FDA's going, uh, there's no asbestos here,</p> <p>22 we can rest assured. What's the big deal?</p> <p>23 That's what your company is saying.</p> <p>24 BY MR. EWALD:</p> <p>25 Q. Okay. So I want you to leave aside</p>	<p style="text-align: right;">Page 204</p> <p>1 A. No.</p> <p>2 MS. O'DELL: Object to the form.</p> <p>3 THE WITNESS: They --</p> <p>4 MS. O'DELL: You may answer.</p> <p>5 THE WITNESS: They missed it.</p> <p>6 Okay.</p> <p>7 Let's -- I mean, if you look at</p> <p>8 their response -- let's just pull up --</p> <p>9 and if I'm correct, they said in response</p> <p>10 that there is not definitive evidence,</p> <p>11 right. The science is not definitive.</p> <p>12 Let me get exactly the words. Give</p> <p>13 me one second. I just want to pull it up.</p> <p>14 Do you mind -- if someone could</p> <p>15 look for the word, whether FDA actually</p> <p>16 said and the word definitive.</p> <p>17 They're responding -- what they</p> <p>18 have in front of them is a request from --</p> <p>19 oh, I'm frozen now.</p> <p>20 BY MR. EWALD:</p> <p>21 Q. I'm sorry. Before you go</p> <p>22 further...</p> <p>23 MR. EWALD: Jake, can you tell me</p> <p>24 which number? I'm having trouble</p> <p>25 finding -- never mind. I found it. Never</p>
<p style="text-align: right;">Page 203</p> <p>1 the asbestos point for a moment because, at</p> <p>2 least as I understand it, the epidemiology</p> <p>3 points that you're making in Section 5 of your</p> <p>4 report are not dependant on whether or not</p> <p>5 there's asbestos in Johnson &amp; Johnson talc,</p> <p>6 correct?</p> <p>7 MS. O'DELL: Object to the form.</p> <p>8 THE WITNESS: I -- I would have to</p> <p>9 go back. I mean, the epidemiology</p> <p>10 independently raises questions, such as</p> <p>11 how the epidemiology negates your ability</p> <p>12 to substantiate the safety in my view.</p> <p>13 You can't say this product -- I</p> <p>14 mean, in light of that epidemiology and</p> <p>15 the totality of that evidence, right,</p> <p>16 you've not -- you've not cleared this</p> <p>17 product. You can't say this product --</p> <p>18 you can't assure the safety of this</p> <p>19 product in light of that epidemiology.</p> <p>20 BY MR. EWALD:</p> <p>21 Q. And you're saying --</p> <p>22 A. That's what Section 5 says.</p> <p>23 Q. And you're saying that the 2014 FDA</p> <p>24 response relied on the wrong standard; they</p> <p>25 screwed up?</p>	<p style="text-align: right;">Page 205</p> <p>1 mind.</p> <p>2 (Whereupon, Exhibit 13, Cancer</p> <p>3 Prevention Coalition Citizen Petition</p> <p>4 Seeking Carcinogenic Labeling on all</p> <p>5 Cosmetic Talc Products, dated November 17,</p> <p>6 1994, was marked for identification.)</p> <p>7 BY MR. EWALD:</p> <p>8 Q. Go ahead, Doctor.</p> <p>9 A. Yeah. So here is -- FDA didn't --</p> <p>10 I mean, we can all -- I don't want to be</p> <p>11 critical of my former agency. But if you look</p> <p>12 at Steven Musser's response, Dr. Musser's</p> <p>13 response, I mean, the growing body of evidence</p> <p>14 to support a possible association between</p> <p>15 genital talc exposure and serious -- serous</p> <p>16 ovarian cancer is difficult to dismiss. The</p> <p>17 evidence is insufficient for FDA to require as</p> <p>18 definitive a warning as you are seeking.</p> <p>19 That is a standard that FDA is</p> <p>20 using. This -- so they are -- they are adding</p> <p>21 the -- they are responding to the petition</p> <p>22 asking for a warning that was definitive.</p> <p>23 Okay. FDA say -- said it could not do that.</p> <p>24 FDA did not respond to the question</p> <p>25 of whether J&amp;J ever substantiated the safety of</p>

<p style="text-align: right;">Page 206</p> <p>1 the product. And there's no need -- if -- if</p> <p>2 FDA believes what your company said for</p> <p>3 50 years that there's no asbestos in their,</p> <p>4 right, we can discuss the role of fibrous talc.</p> <p>5 Leave that aside for the moment. But FDA's</p> <p>6 basically reassured for 50 years that there is</p> <p>7 not a significant risk here because you don't</p> <p>8 have asbestos in it.</p> <p>9 Q. So you keep going back to asbestos.</p> <p>10 And I'm asking you in your</p> <p>11 Section 5 of your report talking about</p> <p>12 epidemiology, you agree with me that does not</p> <p>13 have anything to do with whether or not there</p> <p>14 is asbestos in J&amp;J talc products, correct?</p> <p>15 MS. O'DELL: Object to the form.</p> <p>16 You may answer.</p> <p>17 THE WITNESS: Yeah. No. I</p> <p>18 apologize.</p> <p>19 So I thought you took me out of</p> <p>20 direction. I thought we did five, and</p> <p>21 then you took me outside of five, right,</p> <p>22 to -- with regard to the questioning,</p> <p>23 right?</p> <p>24 BY MR. EWALD:</p> <p>25 Q. Right.</p>	<p style="text-align: right;">Page 208</p> <p>1 can't even remember what --</p> <p>2 A. So go to -- go to paragraph 144.</p> <p>3 Q. No. Hold on.</p> <p>4 A. I'm sorry. Yeah. I thought you --</p> <p>5 I thought were asking.</p> <p>6 Q. No.</p> <p>7 A. I was trying to be helpful. You</p> <p>8 said -- I'm sorry, sir. I apologize.</p> <p>9 Q. So I just want to note here you</p> <p>10 talked about the couple of sentences in this</p> <p>11 2014 paragraph that 2014 response from FDA does</p> <p>12 also note that we are committed to the</p> <p>13 protection of the public health and share your</p> <p>14 risk -- share your interest in reducing the</p> <p>15 risk of ovarian cancer.</p> <p>16 Current regulations state that</p> <p>17 cosmetic products shall bear a warning</p> <p>18 statement whenever necessary or appropriate to</p> <p>19 prevent a health hazard that may be associated</p> <p>20 with a product.</p> <p>21 Do you agree that at the time in</p> <p>22 2014, this was an accurate statement of at</p> <p>23 least one of the regulations that could apply</p> <p>24 to the warning statement on the cosmetic</p> <p>25 product?</p>
<p style="text-align: right;">Page 207</p> <p>1 A. So you are right. Five just says</p> <p>2 in light of the -- in light of the</p> <p>3 epidemiology, there are serious questions that</p> <p>4 question the safety of this product. You</p> <p>5 can't -- you've not assured the safety of the</p> <p>6 product. That's all I say in five, right.</p> <p>7 Q. But --</p> <p>8 A. But the bigger question here -- I</p> <p>9 mean, again -- I'm sorry. Let me stop there,</p> <p>10 sir.</p> <p>11 Q. It's all right.</p> <p>12 A. So the bigger question, right,</p> <p>13 is -- I mean, why is FDA -- you know, I mean,</p> <p>14 is what we've been talking about, which is that</p> <p>15 the risk of the product, I mean, is -- the</p> <p>16 major risk of this product is -- that FDA's</p> <p>17 concerned about is whether asbestos -- there's</p> <p>18 no asbestos. There's no risk. That's an</p> <p>19 overstatement because there's fibrous talc, and</p> <p>20 we have to consider that.</p> <p>21 But the reason FDA's been in its</p> <p>22 seat for 50 years, right, is that there's no --</p> <p>23 you've been saying there's no asbestos in it,</p> <p>24 and it believed you.</p> <p>25 Q. So in this 2014 response -- and I</p>	<p style="text-align: right;">Page 209</p> <p>1 A. I'd have to go back and just --</p> <p>2 you'd have to give me a couple of minutes to</p> <p>3 compare that to the statute. You know, again,</p> <p>4 there's -- as you just correctly said, there is</p> <p>5 this other sort of arcane requirement when you</p> <p>6 don't substantiate, you have to say your</p> <p>7 product is un- -- safety has not been</p> <p>8 substantiated. And that's what FDA is missing</p> <p>9 here.</p> <p>10 So this is only part of this --</p> <p>11 part of the regulations as you eluded to in</p> <p>12 your question.</p> <p>13 Q. Okay. But do you agree that the</p> <p>14 FDA --</p> <p>15 A. I -- I --</p> <p>16 Q. I'm sorry. The FDA accurately</p> <p>17 stated some -- at least one -- one requirements</p> <p>18 in this letter and understood it?</p> <p>19 A. I'd have to go -- we'd have to --</p> <p>20 you'd have to put up the statute and the regs</p> <p>21 for me to opine on that officially on what the</p> <p>22 actual standard.</p> <p>23 I -- whenever necessary or</p> <p>24 appropriate to prevent a health hazard, we just</p> <p>25 have to look at the statute. If that</p>

<p style="text-align: right;">Page 210</p> <p>1 matches -- if those words are exactly out of  2 the statute, then that's fine. I just -- I  3 don't have that committed to memory.  4 Q. That's fine. After the publication  5 of this response 2014, at any point in time did  6 you communicate to anyone past or present at  7 FDA that felt like they misunderstood the  8 standard?  9 A. Did I communicate to anyone since  10 when -- since what -- since when?  11 Q. Since the issuance of this letter  12 on April 1st, 2014.  13 A. Well, I'm not aware of this letter  14 in 2014, I don't believe, okay. I'm not  15 involved.  16 Q. Have you seen this letter before?  17 A. Have I seen it before?  18 Q. I thought you quoted it in your  19 report.  20 A. I'm not -- I'm sorry. Maybe I'm  21 missing.  22 What I simply was saying, I'm  23 certainly aware of the FDA's response, okay, in  24 2014. I'm not aware that I was aware of it on  25 April 1st when it came out. I wasn't at the</p>	<p style="text-align: right;">Page 212</p> <p>1 citizens' petitions from Cancer Prevention  2 Coalition, one dated November 17th, 1994, and  3 the other dated May 13th, 2008, right?  4 A. Yes, sir.  5 Q. And in your report you state on two  6 occasions, in particular on page 59,  7 Footnote 55, that --  8 A. Well, hold -- hold on. Let me get  9 there. I apologize. Let me just get there.  10 Q. Sure.  11 A. Thank you very much. 59,  12 footnote --  13 Q. 55.  14 A. Yes, sir. I'm there.  15 Q. Okay. You state, "As I stated  16 above, based on my recollection, I was not  17 personally and substantially involved in talc  18 matters while commissioner. There were certain  19 letters that were addressed to the commissioner  20 during that time period concerning talc."  21 Did I read that correctly?  22 A. Yes, sir.  23 Q. Okay. And what, if anything, do  24 you remember about the 1994 citizen petition  25 letter relating to talc?</p>
<p style="text-align: right;">Page 211</p> <p>1 agency, and I wasn't involved in this matter.  2 I certainly became aware of this in  3 my studying, in my involvement of this matter.  4 Do you understand?  5 But I wasn't necessarily aware of  6 this in 2014.  7 Does that answer your question?  8 Q. So am I understanding that you  9 weren't aware of this ruling until you started  10 working as an expert in this case, 2016?  11 A. I -- I don't know exactly when I  12 knew that Sam Epstein's petition was turned  13 down. I do not recall the date of that.  14 MR. O'DELL: Hey, you guys, the  15 eclipse is happening now, I think.  16 Can we take a short break?  17 MR. EWALD: Sure.  18 (Whereupon, a break was taken.)  19 BY MR. EWALD:  20 Q. Okay. Doctor, when we left off, we  21 were talking about what we had marked as  22 Exhibit 13, which is the FDA response to  23 citizens' petitions related to talc.  24 And you're aware, am I correct,  25 that this 2014 letter is in response to two</p>	<p style="text-align: right;">Page 213</p> <p>1 A. I remember nothing. I have no  2 recollection about this while I was at FDA. I  3 mean, I have no recollection about this issue  4 either now or then arising during the FDA. I  5 don't have any recollection.  6 Q. And so --  7 A. I went back and checked my book and  8 my years at FDA. I didn't see anything. I  9 believe -- and I -- and I looked at the  10 database to see if I was involved in any  11 matters.  12 I was involved in cosmetic matters,  13 but not involved in talc as I -- as I can  14 recollect.  15 Q. Okay. And just so the record's  16 clear, when you say you were not involved in  17 talc during your tenure as commissioner of the  18 FDA, you're not just specifically talking about  19 the 1994 citizen's petition; you are referring  20 to any issues related to talc whatsoever?  21 A. I have no recollection of any  22 issues pertaining to talc.  23 Now saying that, you know, if you  24 go to the national archives and we FOI it,  25 you're going to see my name on that letter.</p>

<p style="text-align: right;">Page 214</p> <p>1 I'm aware of that. I mean, that came in, or  2 there may have been other correspondence.  3 But I don't remember being involved  4 at all in any matters. That doesn't mean my  5 memory's perfect.  6 Q. Understood. You referred to your  7 book.  8 Just what book are you referring  9 to?  10 A. So I -- I did a book called "A  11 Question of Intent." It was really --  12 primarily it was about my FDA term and  13 primarily about tobacco.  14 Q. And you indicated that you went  15 back and looked at that to see if there was --  16 A. I --  17 Q. -- any mention of any talc?  18 A. I believe I did. I've got to  19 double check, but I don't believe there's  20 anything about talc in that book. If there  21 were -- and it deals with most of the issues  22 that I dealt with while I was FDA commissioner.  23 Q. And you said you also searched the  24 discovery MDL database?  25 A. I just put my name in because I</p>	<p style="text-align: right;">Page 216</p> <p>1 usually got referred. It -- it was a long rich  2 history of citizens' petitions. I mean,  3 tobacco got started. I mean, I got involved.  4 There was a 1988 citizen's petition on tobacco  5 that got submitted that I picked up in 1992.  6 But for the most part, the  7 citizens' petitions will be dealt with by the  8 substantive center for which that petition will  9 be submitted with the subject matter. It will  10 be dealt with by the center and those experts  11 within the center that have, you know,  12 expertise on that matter.  13 And the administrative structure  14 around that center -- obviously, they can come  15 to the commissioner and ask for help; or there  16 are times when a matter, such as tobacco, I  17 mean, is in very significant public view where,  18 you know, I mean, I involve myself, okay, in  19 that matter.  20 Q. All right. And so when this  21 citizen's petition came in and in 1994 to FDA  22 from the Cancer Prevention Coalition, what  23 would be the substantive center that would be  24 directed to you?  25 A. It would -- it would be exec sec.</p>
<p style="text-align: right;">Page 215</p> <p>1 wanted to know whether my recollection was  2 correct, right, whether I -- you know, was I  3 involved.  4 I have -- you know, I didn't see  5 with regard to talc -- again, cosmetic issues,  6 my name came back on a number of cosmetic  7 issues that I remember that I allude to in this  8 report, not on talc.  9 Q. What -- well, am I correct that you  10 were commissioner of the FDA from 1990 to 1997,  11 correct?  12 A. You know, not the entire 1990 to  13 1997; but yes, you're correct.  14 Q. Okay. And during that period of  15 time, what was the typical procedure in your  16 office if a citizen's petition came in on topic  17 addressed to you?  18 A. There were -- I mean, I think I  19 once, in another matter, compiled all the  20 citizens' petitions. I mean, I think if my  21 recollection -- I'd have to go back. There was  22 no shortage of citizens' petitions. You're  23 dealing in quite a large number of citizens'  24 petitions that were -- that were filed, right.  25 And, you know, citizens' petitions</p>	<p style="text-align: right;">Page 217</p> <p>1 It was an exec -- executive organization within  2 the commissioner's office. And it would be  3 assigned there, and it would go down to sift  4 sand; and then it would go to the cosmetic  5 branch within sift sand.  6 Q. And is there any process while you  7 were at FDA in getting commissioner sign-off  8 for responding to a citizen's petition?  9 A. Not that I'm -- not that I'm aware  10 of. That is a delegated authority, and it  11 would be done by the substantive center unless  12 -- unless the center asked for assistance or  13 the commissioner were involved.  14 Q. Do you recall who would have been  15 the individual who ultimately had that  16 delegated authority at FDA when the citizen's  17 petition came in in November 1994?  18 A. So again, if you have the  19 response -- I mean, you note that the response  20 was not until 2014 or 1994, so it's a 20-year  21 history.  22 But my guess is what you will see,  23 for example, on the '88 response, there was a  24 response to a citizen's petition. On the last  25 page of that response, if you have an FDA</p>



<p style="text-align: right;">Page 218</p> <p>1 internal copy, you will see all these codes, 2 right. 3 So I mean, I'm happy to bring it 4 up. 5 THE WITNESS: Do you have the '88 6 petition? 7 I can just use that. 8 You will see all these codes there 9 of different people who are involved in 10 the sign-off. So let me just pull that -- 11 BY MR. EWALD: 12 Q. I'm sorry. I want to make sure 13 we're on the same page. 14 You're talking about the calculated 15 one in '86? 16 A. Yeah. What was -- what was the 17 response? 18 What year was the response? The 19 response was '86? 20 Q. It was '86, I believe. I might be 21 wrong, but -- 22 A. The one by Dick Swanson. 23 When did Dick Swanson respond? 24 Q. I believe '86. 25 A. So you're right. I am -- it's '86.</p>	<p style="text-align: right;">Page 220</p> <p>1 to that process when you came along as 2 commissioner in 1990? 3 A. No. In fact, if anything, there 4 were -- there was a huge backlog on citizens' 5 petitions. I mean, there were petitions that 6 were held over from the '80s that I was dealing 7 with still that had never gotten answered. 8 And as you can see, the 1994 9 petition got answered in 2014. 10 Q. So do you have any knowledge at all 11 how FDA was responding, if at all, to the 1994 12 citizens' petitions while you were commissioner 13 through some point in 1997? 14 A. No. I -- as I said, I've had no -- 15 I have no recollection of this issue whatsoever 16 during that time period. 17 Q. The footnote that I read a few 18 moments ago on page 59 says that there were 19 certain letters that were addressed to the 20 commissioner during that time period concerning 21 talc. 22 I'm specifically looking at the 23 plural "letters." 24 Are you aware of any letters other 25 than the 1994 citizen's petition from Cancer</p>
<p style="text-align: right;">Page 219</p> <p>1 So if you go, for example, to page 4 of that, 2 right. 3 Q. Hold on. Is that the page? 4 A. Yeah. So just as an example, so 5 leave aside the cc's because that's where 6 copies went, right; and those are where it got 7 filed, but you can see who prepared it, who 8 initialed it and where it was circled, right. 9 So I'm blocking. Commissioner 10 Frank -- what was Frank's last name? I'm 11 blocking. I don't see the commissioner's name 12 here as having signed off on this, for example. 13 Most of these are either -- John 14 Taylor was regulatory affairs. Gary Flamm was 15 mostly -- Bob Lake -- this as all sift sand 16 directed people. Derfler was general counsel, 17 right. Linda Horton was general counsel, 18 right. 19 So this is general counsel, and the 20 center responded, with John Taylor at 21 regulatory affairs also taking the lead. 22 So that would give you a sense. 23 That was the process in '86. 24 Q. Okay. And did -- are you aware of 25 any change -- well, are you aware of any change</p>	<p style="text-align: right;">Page 221</p> <p>1 Prevention Society relating to talc? 2 A. You know, you're right. That could 3 be an error. That could be accurate. I'd have 4 to go back and check the database. I mean, it 5 would be in your discovery database. You can 6 just -- 7 I mean, as we sit here right now, 8 the only one that I can visualize -- and I 9 mean, now from my studying this, not when the 10 time it came in -- more recently that was the 11 Sam Epstein that was addressed to me. 12 Q. All right. So let's mark as 13 Exhibit 14, the 1994 letter. I will drop it in 14 the chat. Just give me a second. 15 MR. EWALD: I've got this one, 16 Jake. 17 (Whereupon, Exhibit 14, Letter 18 dated November 17, 1994, with enclosure of 19 Citizen Petition Seeking Carcinogenic 20 Labeling on all Cosmetic Talc Products, 21 was marked for identification.) 22 THE WITNESS: Can we get these 23 other screens going? 24 I'm afraid to touch anything. 25 MS. O'DELL: John, I'm just going</p>

<p style="text-align: right;">Page 222</p> <p>1 to adjust something for a minute here, so</p> <p>2 keep putting it in the chat.</p> <p>3 THE WITNESS: Yeah. I've lost</p> <p>4 those other monitors.</p> <p>5 Does anyone have an iPad that I can</p> <p>6 kindly pull up with the documents?</p> <p>7 I've lost my two other monitors for</p> <p>8 the moment.</p> <p>9 So, Mr. Ewald, I'm going to borrow</p> <p>10 someone else's iPad so I can look at this</p> <p>11 document so I don't take you off the</p> <p>12 screen.</p> <p>13 BY MR. EWALD:</p> <p>14 Q. Sure.</p> <p>15 A. Thank you, sir.</p> <p>16 Let me -- I'm happy if you could</p> <p>17 try to do this without my flashing on the</p> <p>18 screen, let's -- not to hold you up I'm</p> <p>19 happy --</p> <p>20 MR. EWALD: There's two ways to do</p> <p>21 it. We can try going forward with that,</p> <p>22 or we also can go off the record. I just</p> <p>23 don't want my time going into the</p> <p>24 difficulties. I'm not saying suggesting</p> <p>25 you want that either. I'm just saying</p>	<p style="text-align: right;">Page 224</p> <p>1 put on to a docket; yes, sir.</p> <p>2 Q. Okay. And it states, among other</p> <p>3 things, that this citizen's petition is based</p> <p>4 on scientific papers dating back to the 1960s,</p> <p>5 which warned of increased cancer rates</p> <p>6 resulting from frequent exposure to cosmetica</p> <p>7 grade talc.</p> <p>8 That's what it says right?</p> <p>9 A. Right.</p> <p>10 Q. And then if we scroll down in the</p> <p>11 formal -- formal part of the petition, it</p> <p>12 states that research done as early as 1961 has</p> <p>13 shown that particles similar to talc and</p> <p>14 asbestos particles can translocate from the</p> <p>15 exterior genital area to the ovaries in women.</p> <p>16 Do you see that?</p> <p>17 A. I do.</p> <p>18 Q. "These findings provide support to</p> <p>19 the unexpected high rate of mortality from</p> <p>20 ovarian cancer in female asbestos workers.</p> <p>21 Minute particles such as talc are able to</p> <p>22 translocate through the female reproductive</p> <p>23 tract and cause foreign body reactions in the</p> <p>24 ovaries."</p> <p>25 Did I read that correctly?</p>
<p style="text-align: right;">Page 223</p> <p>1 it's up to you guys.</p> <p>2 MS. O'DELL: We've got it right</p> <p>3 here. So just give us a second.</p> <p>4 MR. EWALD: Okay.</p> <p>5 MS. O'DELL: Sorry. I don't know</p> <p>6 what happened to our screen.</p> <p>7 (Discussion held off the record.)</p> <p>8 THE WITNESS: Okay. Okay. I'm</p> <p>9 back.</p> <p>10 MS. O'DELL: It's opening now,</p> <p>11 John.</p> <p>12 MR. EWALD: Leigh, let's go off the</p> <p>13 record.</p> <p>14 (Whereupon, a break was taken.)</p> <p>15 BY MR. EWALD:</p> <p>16 Q. So I marked before the cutoff as</p> <p>17 Exhibit 14 the 1994 citizen's petition. I'll</p> <p>18 pull it up on the screen.</p> <p>19 A. I have it, sir.</p> <p>20 Q. Great. And so for the record, this</p> <p>21 is from Cancer Prevention -- Cancer Prevention</p> <p>22 Coalition, dated November 17th, 1994; and it's</p> <p>23 directed to Commissioner Kessler, correct?</p> <p>24 A. It comes in as to the dockets</p> <p>25 manager in brand, so it's specific -- it gets</p>	<p style="text-align: right;">Page 225</p> <p>1 A. You did.</p> <p>2 Q. And then it goes on to say, "There</p> <p>3 is a large body of scientific evidence dating</p> <p>4 back 30 years on the toxicity and mineralogy of</p> <p>5 cosmetic talc products. As early as 1968,</p> <p>6 Cralley, et al., concluded"; and there's an</p> <p>7 entry there from Cralley.</p> <p>8 And am I correct that you cite to</p> <p>9 the Cralley article a couple of times in your</p> <p>10 report?</p> <p>11 A. I think that's correct.</p> <p>12 Q. And then it also cites to a paper</p> <p>13 from Rohl examining 21 samples of consumer</p> <p>14 talcums and powders --</p> <p>15 A. Right.</p> <p>16 Q. -- which 1971 to 1975.</p> <p>17 Is that an article you're familiar</p> <p>18 with?</p> <p>19 A. Yep.</p> <p>20 Q. Okay. And then it continues on</p> <p>21 with discussion of the epidemiology, including</p> <p>22 the Cramer 1982 study, correct?</p> <p>23 A. Let's see where you are, what page.</p> <p>24 You're at Harlow on 4.</p> <p>25 Q. Right.</p>

<p style="text-align: right;">Page 226</p> <p>1 A. Cramer is cited in Number 17 2 footnote. 3 Q. Right. In your view is the 4 evidence that's presented in the citizen's 5 petition sufficient to show that there may 6 be -- that a warning label should have gone on 7 talcum powder products as of 1994? 8 A. Let me understand your question. 9 You're asking whether the statement -- does it 10 support the evidence that talcum powder causes 11 cancer in laboratory animals. Frequent talc 12 application in the female genital increases the 13 risk of ovarian cancer. So you're asking for a 14 causation standard in laboratory animals where 15 the evidence -- 16 Q. No. 17 A. -- supports that? I'm sorry. 18 Q. No. I'm sorry. And I -- it may 19 well -- the problem may be on my end. 20 I'm asking you, from the standards 21 that you are citing, the regulatory standards 22 from the FDCA and CFR that you quote in your 23 report relating to warning and substantiate 24 safety, does the evidence that's presented in 25 this 1994 citizen's petition directed to you,</p>	<p style="text-align: right;">Page 228</p> <p>1 supported -- at this time that would support a 2 warning that the safety has not been 3 substantiated. 4 That's your question? 5 Q. That's one of my questions. Let's 6 start with that one. 7 A. Feel free to ask any question you 8 want. I don't want -- 9 Q. I said that's one of my questions, 10 so that's the question I'm asking first. 11 A. So I believe that if you ask that 12 question -- and again, I'd have to -- I don't 13 want to -- I would want to go back and look 14 exactly what is cited in this letter, right. 15 I'd want to make a list of what is cited in 16 this letter. 17 But what I can tell you is that as 18 of 1994, certainly this is the -- the -- the 19 safety of the product was not substantiated and 20 would require a warning that it's not 21 substantiated. 22 It's a little arcane FDA 23 requirement in the act. It's a -- in essence, 24 no one's going to want to put that statement 25 on. You're going to pull the product. I mean,</p>
<p style="text-align: right;">Page 227</p> <p>1 in your mind, require a warning on talcum 2 powder products? 3 A. I'm confused because there's a 4 specific warning that it is requested that is 5 the subject of this. You're asking me whether 6 it's -- whether there's a different warning -- 7 Q. Yes. 8 A. -- that would be substantiated. 9 Q. Yes. I'm saying don't worry about 10 the specific warning that's asked. I'm asking 11 you on the evidence that's presented in this 12 1994 letter directed to you, understanding that 13 it didn't go directly to you, but it's directed 14 to you, whether or not the evidence presented 15 there is sufficient -- 16 A. Yeah. 17 Q. -- to require a warning under the 18 rules and regulations that you cite in your 19 report. 20 A. So just to be clear on what warning 21 we're talking about that I am saying -- that we 22 are -- whether we are talking about the safety 23 of the product has not been substantiated, that 24 would be the warning. 25 Is there evidence in this that</p>	<p style="text-align: right;">Page 229</p> <p>1 that's the essence; but Congress, you know, 2 gets to set the standard, and they say if you 3 don't substantiate, you have to say you don't 4 substantiate. Maybe a few people have done 5 that. But that's -- you know, it's just 6 basically, you don't put a product on if you 7 can't substantiate its safety. 8 But there's no doubt by 1994 -- and 9 even we talked about in 1970 -- the product 10 safety was not assured; and therefore, you have 11 to, with the evidence that was in place and 12 certainly in the '70s, '80s, and '90s. 13 Once you know, okay, once you -- 14 once you know that asbestos is in this product, 15 it becomes a slam-dunk, right, that not only 16 should there be a warning, the product 17 shouldn't be sold. 18 So by 1994 this product should -- 19 once you recognize there's asbestos in this 20 product, okay, and you can't assure that 21 asbestos is not in this product, this product 22 shouldn't be sold. 1994, 1970. 23 Q. Okay. 24 A. That's not what FDA is focused on 25 because FDA is focused on whether the petition</p>

<p style="text-align: right;">Page 230</p> <p>1 makes the support for the petitioner's -- 2 petitioner's request, right. That's what FDA 3 is paying attention to. 4 And in the background of this, I 5 mean, certainly, we knew through the late '80s 6 we have evidence that FDA really thought that 7 there wasn't -- there was no asbestos in this 8 stuff. You -- the -- J&amp;J, in essence, 9 convinced the agency that there's no asbestos 10 in this. They bought -- they bought that. 11 Q. So we talked about the warning and 12 safety of this product has not been determined. 13 What about the requirement that you 14 talk about in your report that the cosmetics 15 label shall bear a warning statement whenever 16 necessary or appropriate to prevent a health 17 hazard that may be associated with the product? 18 Is it your view based on the 19 evidence that is described in this citizen's 20 petition letter of 1994 directed to you that it 21 is sufficient to require a warning statement 22 because it needs to prevent a health hazard 23 that may be associated with the product? 24 A. Could you just show me the 25 paragraph --</p>	<p style="text-align: right;">Page 232</p> <p>1 A. Absolutely. And I -- and I 2 appreciate your hypothetical, right. I 3 think -- I have no doubt in my mind, once you 4 understand that asbestos is in talc, right, you 5 have a duty, one, not to -- I mean, the product 6 becomes adulterated. And if you are so 7 misguided you continue to sell it, right -- I 8 mean, why would you want to sell an adulterated 9 product? So that's the first step here. 10 Now, so -- so you want to sell an 11 adulterated product, but you're going to -- of 12 course you would have to put that label on it, 13 but that doesn't get you out of the 14 adulteration. 15 Once your -- once there's asbestos 16 in this product, it's over, as your company has 17 finally recognized by pulling the product. 18 You don't -- in 2019 you didn't put 19 a label on it, oh, FDA found asbestos. You 20 pulled the product. That's what you would do. 21 A hypothetical, you know, again, I 22 mean, it's an interesting -- you can talk about 23 a legal standard, but the core responsibility 24 is not to sell an adulterated product; and you 25 don't sell products that have asbestos in it,</p>
<p style="text-align: right;">Page 231</p> <p>1 THE WITNESS: I'm sorry, Counsel. 2 MS. O'DELL: That is my question. 3 Yes. 4 THE WITNESS: Paragraph 31. 5 MS. O'DELL: Could you repeat your 6 question, please, John? 7 MR. EWALD: Sure. 8 BY MR. EWALD: 9 Q. My question is: Based on the 10 evidence that is cited in this 1994 citizen's 11 petition letter directed to Dr. Kessler, is it 12 sufficient, in your mind, to require a label on 13 talc products that contains a warning statement 14 to prevent a health hazard that may be 15 associated with the product? 16 A. Are you -- I'm not -- are you 17 saying that I made that as one of my opinions 18 in this report? 19 Are you asking a -- 20 Q. No. I'm asking you a hypothetical. 21 A. So you're asking me to go beyond my 22 report and what's my opinion? 23 Q. I'm asking a hypothetical, which 24 is, as you know, it's been done for a long 25 time. It's perfect for expert witnesses.</p>	<p style="text-align: right;">Page 233</p> <p>1 and it had asbestos in it. 2 Q. Doctor, I'm not talking about 2019 3 right now. I'm not talking 2024. 4 I'm asking you, hypothetically, the 5 evidence that is contained in this citizen's 6 petition from 1994 directed to you, in your 7 mind, is it sufficient to require a warning at 8 that time that talc products implicates 9 21 CFR 740.10, there should a warning statement 10 whenever necessary appropriated to prevent a 11 health hazard that may be associated with a 12 product. That's my question. 13 MS. O'DELL: Object to the form. 14 THE WITNESS: And the point of 15 clarification that I would need to know 16 from you in your hypothetical is, is 17 asbestos in your product in your 18 hypothetical. 19 BY MR. EWALD: 20 Q. I -- I am -- the only hypothetical 21 part about it is you making the decision on it. 22 I want you to assume that this 23 state of knowledge at the FDA and publicly is 24 the same as it actually historically was and is 25 reflected in this document.</p>

<p style="text-align: right;">Page 234</p> <p>1 MS. O'DELL: Object to the form. 2 Incomplete hypothetical. 3 You may answer it anyway you'd 4 like, Doctor. 5 MR. EWALD: Well, he can't answer 6 any -- 7 THE WITNESS: I'm happy -- 8 MR. EWALD: He has -- 9 THE WITNESS: I -- I'm happy to -- 10 MR. EWALD: He has to answer it 11 truthfully. 12 BY MR. EWALD: 13 Q. You have to answer it truthfully, 14 but go ahead. 15 MS. O'DELL: So that's not the 16 question, John. The question is you're 17 directing a certain response from 18 Dr. Kessler, and my instruction to him was 19 he may answer in any way he feels 20 appropriate. He doesn't have to comply 21 with your request, but he we object to the 22 form of the question. 23 THE WITNESS: In 1994, to answer 24 the question this way, if I were -- if I 25 were -- if I knew as commissioner, right,</p>	<p style="text-align: right;">Page 236</p> <p>1 1970s. It got the testing results. The 2 industry walked in -- J&amp;J walked in and 3 said, no problem, we've got this under 4 control; we have a testing method. 5 That statement's repeated in the 6 literature for decades. FDA believes 7 that. That's why your getting these -- 8 FDA's responding like this. You know, 9 level with the agency. There's asbestos 10 in it. This is over. 11 BY MR. EWALD: 12 Q. So we'll get to the agency's 13 response and what happened in 1970s, but you 14 keep on avoiding my question. 15 I want you to leave your 16 asbestos -- is your opinion that if there's no 17 asbestos, then there's no problem? 18 MS. O'DELL: Object to the form. 19 THE WITNESS: No. No, I didn't say 20 that. And as -- 21 BY MR. EWALD: 22 Q. Okay. 23 A. I mean, I think that whenever 24 there's fibers -- mineralogical fibers that 25 have biological activity, there's an issue.</p>
<p style="text-align: right;">Page 235</p> <p>1 that talc had asbestos, if J&amp;J walked in 2 and told me that, right, that product 3 would be off the market. 4 So I didn't know in 1994 that talc 5 contained asbestos. Okay. We know in 6 1988, if you look at the documents, right, 7 that we see that FDA believes that the 8 1976 testing J4-1 testing requirements 9 dealt with the issue and assured the 10 public there was no asbestos, right. 11 If there's asbestos in this product 12 and I were commissioner, there would be -- 13 we're not talking about a warning -- the 14 product's not being sold. 15 And I mean, I'm sure your 16 company -- I mean, your company would not 17 have fought me on that. I mean, any 18 commissioner gets up, there's asbestos in 19 this product. It shouldn't be sold. I 20 mean, that's a given. 21 The central question is when -- 22 when does FDA know that and is convinced 23 there's asbestos in this product. It had 24 a great deal of suspicion and evidence 25 that there was some problem in the early</p>	<p style="text-align: right;">Page 237</p> <p>1 I'm just saying let's leave that issue aside 2 for the moment, right. 3 This really depends on this last 4 50-year history is -- you know, FDA believing 5 there's no asbestos in this. 6 Q. And what do you -- and you keep 7 saying that. But what -- well, let's break 8 that down. 9 From your time period, which you 10 have the, you know, most personal knowledge 11 presumably, from 1990 to 1997, your testimony's 12 been you have no idea that it was even possible 13 that there could be asbestos in talc, right? 14 A. Possible, and I don't -- I don't 15 know whether I had that. I certainly did not 16 connect -- I did not connect that there was 17 asbestos in talc. That was not part of my -- 18 my universe. 19 Q. Okay. And so when it's responded 20 in 2014, you're intimating some under the 21 intent from the FDA about it being due to the 22 fact that they thought there was no asbestos; 23 yet, you didn't even know it was -- got issued 24 at the time was your prior testimony, correct. 25 MS. O'DELL: Object to --</p>



<p style="text-align: right;">Page 238</p> <p>1 THE WITNESS: I'm out of the --</p> <p>2 MS. O'DELL: -- object to the form.</p> <p>3 THE WITNESS: I'm out of the</p> <p>4 agency. I don't have a duty. I mean, I'm</p> <p>5 not running the agency in 2014, so I'm not</p> <p>6 sure I understand your question.</p> <p>7 You look at the record --</p> <p>8 BY MR. EWALD:</p> <p>9 Q. Let me --</p> <p>10 A. Let me finish the answer to my</p> <p>11 question, please.</p> <p>12 Q. Okay.</p> <p>13 A. If you look at the record, what we</p> <p>14 do have, okay, is in 1988 in the response; and</p> <p>15 if you look at the record in 1988, right, FDA</p> <p>16 believes -- just look at the -- just look at</p> <p>17 the -- I mean, even just --</p> <p>18 Q. I'm looking at it. It's '86,</p> <p>19 though, right?</p> <p>20 A. It's '86. I'm sorry. You're</p> <p>21 right, Mr. Ewald. Thanks for the correction.</p> <p>22 I appreciate it. You're absolutely right. I</p> <p>23 stand corrected.</p> <p>24 In that '86 letter, you look at</p> <p>25 what Swanson says, right, it's that the</p>	<p style="text-align: right;">Page 240</p> <p>1 MR. EWALD: And this is "Talc:</p> <p>2 Consumer Uses and Health Perspectives."</p> <p>3 We'll make this Exhibit 15. It's dated</p> <p>4 October 1, 1994. It's cosponsored by the</p> <p>5 International Society of Regulatory</p> <p>6 Toxicology &amp; Pharmacology and the United</p> <p>7 States Food and Drug Administration.</p> <p>8 (Whereupon, Exhibit 15, Document</p> <p>9 entitled, "Talc: Consumer Uses and Health</p> <p>10 Perspectives," dated October 1, 1994,</p> <p>11 cosponsored by the International Society</p> <p>12 of Regulatory Toxicology &amp; Pharmacology</p> <p>13 and the United States Food and Drug</p> <p>14 Administration, was marked for</p> <p>15 identification.)</p> <p>16 BY MR. EWALD:</p> <p>17 Q. And then you see, Doctor, on the</p> <p>18 first two pages, you have a list of</p> <p>19 participants, correct?</p> <p>20 A. Yep.</p> <p>21 Q. And the list of participants</p> <p>22 include a number of folks from FDA, correct?</p> <p>23 A. Yep.</p> <p>24 Q. Including in that is someone from</p> <p>25 your office, correct?</p>
<p style="text-align: right;">Page 239</p> <p>1 industry put into -- put in J4-1 and that</p> <p>2 assures the public that the risk is minimized.</p> <p>3 That was not the case.</p> <p>4 And you see that that -- the</p> <p>5 support that there is not asbestos in the</p> <p>6 product, right, is -- I mean, in that record to</p> <p>7 that response. So again, it's all based on the</p> <p>8 fact that you fixed the problem with J4-1, and</p> <p>9 you didn't.</p> <p>10 Q. All right. Doctor, are you</p> <p>11 familiar with a symposium held in October 1994</p> <p>12 that was cosponsored by the FDA related to</p> <p>13 talc?</p> <p>14 A. A workshop?</p> <p>15 Q. Yes.</p> <p>16 A. And I have my workshop notes, yes.</p> <p>17 I have gone back and studied that, yes, sir.</p> <p>18 Q. Okay. And so I take it from your</p> <p>19 earlier testimony that you have no recollection</p> <p>20 whatsoever of having any involvement with that</p> <p>21 workshop and any statements about that?</p> <p>22 A. I have no recollection of that</p> <p>23 workshop taking place during the time I'm at</p> <p>24 commissioner. I have studied that since then.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 241</p> <p>1 A. I think Merkatz is listed.</p> <p>2 Q. I see Carol Schmenan?</p> <p>3 A. Carol Schmenan, yeah.</p> <p>4 Q. It says Carol Schmenan, U.S. Food &amp;</p> <p>5 Drug Administration Commissioner's Office,</p> <p>6 right.</p> <p>7 A. Right.</p> <p>8 Q. Do you remember Carol?</p> <p>9 A. Yes. She was there, yep.</p> <p>10 Sorry?</p> <p>11 Q. Do you remember Carol?</p> <p>12 A. Yes.</p> <p>13 Q. Do you think highly of Carol.</p> <p>14 A. Very much so. Great public</p> <p>15 servant.</p> <p>16 Q. So the executive summary -- this</p> <p>17 is, by the way, published in the Regulatory</p> <p>18 Toxicology and Pharmacology in 1995 and talks</p> <p>19 about: "This issue of the journal is largely</p> <p>20 dedicated to report on a January 31-February 1,</p> <p>21 1994, workshop on talc organized in a joint</p> <p>22 sponsorship of the U.S. Food &amp; Drug</p> <p>23 Administration; the Cosmetics, Toiletries, and</p> <p>24 Fragrances Association (CTFA); and the</p> <p>25 International Society of Regulatory Toxicology</p>

<p style="text-align: right;">Page 242</p> <p>1 and Pharmacology (IS RTP). Although not all 2 papers given at the meeting were made available 3 for publication, this offers a general overview 4 of the substance of the presentations and 5 discussions." 6 And after discussing some aspects, 7 it talks about Dr. Gilbertson. 8 Are you familiar with 9 Dr. Gilbertson? 10 A. I know the name, certainly, yes. 11 Q. Okay. Do you have any -- what 12 is -- what is your recollection of what kind of 13 public servant Dr. Gilbertson was? 14 A. I -- I'm -- I'm trying to place 15 him. I'm drawing a blank for the moment. I'm 16 sure he was a dedicated public servant. 17 Q. And so it says here in these 18 minutes that Dr. Gilbertson FDA reviewed the 19 harmonization of international standards and 20 regulations for cosmetic talc in its consumer 21 application. In their joint evaluation, talc 22 has proven to be among the safest of all 23 consumer products." 24 That's what is relayed, right? 25 A. Yeah. That's what's written there,</p>	<p style="text-align: right;">Page 244</p> <p>1 document that's -- I'll give you the Bates 2 number. It's a J&amp;J document. It's minutes, 3 talc-interested party, shows how that was 4 written, right, by the industry, paid for by 5 the industry. 6 And when you go through -- and I 7 did this because I was interested, and I give 8 it to you. I mean, I just quickly tried to 9 compare what was done in the transcript of that 10 meeting to what was in that article, and they 11 don't match. 12 In fact, if you look at the 13 conclusion of that article, it says there was a 14 conclusion made. In fact, there was no 15 conclusion made. There was some independent 16 statements. And if you look at individual -- 17 how that article was -- what that article 18 alleges that certain people say, that's not 19 what their testimony said. 20 So there is a major problem with 21 that article, and you should just be aware of 22 that. 23 Q. Okay. And just so the record's 24 clear, you say what was the fact and what was 25 not.</p>
<p style="text-align: right;">Page 243</p> <p>1 sir. 2 Q. Okay. All right. Now let's look 3 at -- 4 A. Are you implying -- I just want to 5 make sure -- 6 Q. There is no -- there's no question 7 pending, Doctor. 8 A. Okay. So you're not saying that 9 Carol Schmenan and Mr. Gilbertson had anything 10 to do with that -- that article? 11 I just want to make sure the 12 record's clear. 13 Q. Well, are you suggesting that the 14 article misrepresents what was stated at the 15 workshop? 16 A. Yes, I am. And, in fact, if you go 17 back -- if you go back and look -- and I'm 18 referring you to draft minutes of the talc 19 interested party task force dated July 25th, 20 1994, right, of the CTFA, what is striking 21 about that article that you just showed me, 22 right, that that group of industry officials, 23 right, decide to pay for an overview. 24 The FDA is not at that meeting. 25 This article was paid for by the CTFA, and this</p>	<p style="text-align: right;">Page 245</p> <p>1 You were not at the meeting, right? 2 You have no recollection of ever 3 hearing about that meeting, correct? 4 A. That's correct. But what you do 5 have -- I mean, but what I can do right, I 6 think objectively, is we do -- I have the 7 transcript. I've gone through the transcript 8 of that meeting and what was said. So while I 9 wasn't there, I have the words of everything 10 that was said. 11 There was a verbatim transcript of 12 every presentation and of every word. That's 13 usual for a workshop like that. That -- that 14 work -- that workshop transcript doesn't match 15 that article. That's a head scratcher. 16 And then you go -- well, that's 17 not -- a workshop -- if you look at that 18 article, there's a conclusion that basically 19 was, well, safety is -- I forget what the last 20 paragraph exactly says. But that was never -- 21 that was never the conclusion at the meeting, 22 nor was -- so I go back and I go who paid for 23 this? Who wrote this? 24 You just seem to imply that 25 Gilbertson and Schmenan were part of this.</p>

<p style="text-align: right;">Page 246</p> <p>1 Yeah, they showed up at this meeting; but the</p> <p>2 industry wrote this, and that article does not</p> <p>3 represent what happened at that meeting. Go</p> <p>4 look at the transcript.</p> <p>5 Q. Okay. So you are suggesting that</p> <p>6 when the publicly available article's been out</p> <p>7 there since 1995 says what Dr. Gilbertson and</p> <p>8 the FDA says, that's just wrong?</p> <p>9 MS. O'DELL: Object to the form.</p> <p>10 THE WITNESS: I'm saying that I --</p> <p>11 I mean, I can -- if you look, for example,</p> <p>12 okay -- and I'm happy to give you -- just</p> <p>13 compare what Hartge says with what is</p> <p>14 reported to say. Look at the conclusion.</p> <p>15 Try to find that conclusion in the</p> <p>16 transcript. It doesn't exist.</p> <p>17 BY MR. EWALD:</p> <p>18 Q. Doctor, I have limited time. I</p> <p>19 just want to be --</p> <p>20 A. You're going to show me an article,</p> <p>21 sir, and find --</p> <p>22 Q. Wait. The way this works, Doctor,</p> <p>23 is your counsel can ask you questions about it,</p> <p>24 but you can't go off on your own and --</p> <p>25 A. You showed me an article --</p>	<p style="text-align: right;">Page 248</p> <p>1 the safest of all consumer products."</p> <p>2 So my question to you, Doctor, is:</p> <p>3 Do you have any basis at this point in time to</p> <p>4 tell me that Dr. Gilbertson didn't say what was</p> <p>5 reported in his publicly available article?</p> <p>6 A. We can look exactly at the</p> <p>7 transcript. I can tell you there are other</p> <p>8 statements in that article, right, that were</p> <p>9 never made. I can assure of that.</p> <p>10 I can't -- I -- I will go back and</p> <p>11 look at that statement. We can -- we can look</p> <p>12 at that statement, but there are the statements</p> <p>13 and the conclusion of that article is</p> <p>14 misleading.</p> <p>15 Q. Okay.</p> <p>16 A. Because it never happened at that</p> <p>17 meeting and that -- you just note that on the</p> <p>18 record.</p> <p>19 Q. Okay. Let's do --</p> <p>20 MR. EWALD: Jake, can you -- I'm</p> <p>21 having trouble pulling up on page 88 of</p> <p>22 the outline, starts at 17.04.</p> <p>23 Do you have that?</p> <p>24 MR. KEESTER: I can look. Hold on.</p> <p>25 MR. EWALD: Jake, find that one,</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. Hold on.</p> <p>2 A. You showed me an article -- I'm</p> <p>3 sorry. Let's not talk over each other.</p> <p>4 You showed me an article, and you</p> <p>5 implied that Carol Schmenan and Dr. Gilbertson</p> <p>6 wrote -- I mean, wrote that article. And what</p> <p>7 I'm making sure that the record is clear is</p> <p>8 that article was paid for and written for by</p> <p>9 the industry and doesn't represent, certainly,</p> <p>10 the conclusions of what happened at that</p> <p>11 meeting, and that's a problem.</p> <p>12 Q. What I asked you, Doctor, was</p> <p>13 whether Carol Schmenan and, amongst others,</p> <p>14 Dr. Gilbertson were workshop participants at</p> <p>15 this workshop; and I read to you what was</p> <p>16 represented in the publicly available published</p> <p>17 article about what Dr. Gilbertson said.</p> <p>18 A. You didn't show me -- you did not</p> <p>19 show me the transcript.</p> <p>20 Q. Excuse me. Excuse me. I am still</p> <p>21 asking the question. I would ask for you to</p> <p>22 please wait for my question to be finished.</p> <p>23 A. Of course.</p> <p>24 Q. This says, "In their joint</p> <p>25 evaluation, talc has been proven to be among</p>	<p style="text-align: right;">Page 249</p> <p>1 and also find the one on page 9017.007. I</p> <p>2 want to move on to something else.</p> <p>3 Thank you.</p> <p>4 BY MR. EWALD:</p> <p>5 Q. Let's look at -- quickly at the FDA</p> <p>6 1986 petition.</p> <p>7 Sorry. What?</p> <p>8 A. I asked Margaret if I can just get</p> <p>9 my copy of that. I was trying to help you.</p> <p>10 Q. No worries.</p> <p>11 A. I have the copy of the petition,</p> <p>12 sir. No. I have the copy of the response. I</p> <p>13 don't have a copy of the petition, sir.</p> <p>14 Q. Yeah. I'm just going over the</p> <p>15 response, at least right now.</p> <p>16 A. Thank you, sir.</p> <p>17 MR. EWALD: Okay. We'll mark this</p> <p>18 as exhibit as -- is it -- Suzanne, is this</p> <p>19 16?</p> <p>20 I got distracted.</p> <p>21 THE COURT REPORTER: This should be</p> <p>22 16 according to my notes.</p> <p>23 MR. EWALD: All right. Cool. So</p> <p>24 this will be the 1986 FDA response to</p> <p>25 citizen's petition.</p>

<p style="text-align: right;">Page 250</p> <p>1 (Whereupon, Exhibit 16, The United 2 States Food &amp; Drug Administration's 3 response to the 1986 citizen's petition, 4 was marked for identification.) 5 BY MR. EWALD: 6 Q. All right. And we talked about 7 this is a couple of times earlier today, 8 Doctor. 9 This is something that you have 10 reviewed at some level? 11 A. Yes, sir. 12 Q. All right. I'm going to make it a 13 little bit larger. So -- 14 A. But just for the sake of te -- just 15 put it in the chat if you don't mind so I can 16 put it up on the screen. I have a copy, but 17 this would be very helpful. Let me just -- 18 THE WITNESS: Could you close this? 19 I'm afraid -- there we go. Thanks 20 so much. 21 You can keep on asking questions 22 while he does that. 23 MR. KEESTER: That's fine. I put 24 it in. 25 MR. EWALD: Is this D-205?</p>	<p style="text-align: right;">Page 252</p> <p>1 says -- am I correct -- it contains -- does not 2 contain significant amounts of asbestiform 3 minerals, right? 4 A. That's what it says, but keep on 5 reading -- 6 Q. Right. 7 A. -- reading. 8 Q. "During the early 1970s, FDA became 9 concerned about the possibility that cosmetic 10 talc that contains significant amounts of this 11 material. The agency received several reports 12 about such contamination. However, at that 13 time the analytical procedures for determining 14 asbestos in talc were not fully developed, and 15 most of the analytical work was conducted 16 without scientific agreement as to which 17 methods were well-suited for identification of 18 asbestiform minerals in talc. Consequently FDA 19 considered all analytical results to be of 20 questionable reliability." 21 Did I read that correctly? 22 A. You did, sir. 23 Q. And did you conduct any kind of 24 investigation as to the reliability of test 25 results for the presence of asbestos in the</p>
<p style="text-align: right;">Page 251</p> <p>1 MS. O'DELL: That was the previous. 2 MR. EWALD: I'm sorry. Thank you. 3 BY MR. EWALD: 4 Q. This is -- 5 A. You love the red and gold? 6 Q. Oh, yeah. It's very official. 7 D-7214 and we go to the response to 8 the citizen's petition. It shows up on page 3 9 of the PDF. 10 It says, "This responds to your 11 November 8, 1983, petition requesting that 12 cosmetic talc be labeled with an asbestos 13 warning statement." 14 And it talks about how "FDA 15 recognizes that asbestos inhalation over 16 extended periods is hazardous to humans. The 17 agency is also aware that some cosmetic talc 18 produced in the 1960s and early 1970s did 19 contain asbestiform minerals. However, your 20 petition has not persuaded us that the cosmetic 21 talc that is presently being produced contains 22 significant amounts of asbestiform minerals." 23 And on that point, Doctor, the 24 letter doesn't say that the cosmetic talc 25 contains no asbestiform minerals, but it</p>	<p style="text-align: right;">Page 253</p> <p>1 early to mid-1970s? 2 A. Which test results are we talking 3 about? 4 Q. I'm talking about -- this is 5 referring to at that time in the early 1970s 6 the analytical procedures for determining 7 asbestos in talc were not fully developed and 8 most of the analytical work was conducted 9 without scientific agreement as to which 10 methods were well-suited for identification 11 asbestiform minerals in talc. 12 My question to you is: Do you have 13 any basis to disagree with the FDA's statement 14 here in 1986 on that front? 15 MS. O'DELL: Object to the form. 16 THE WITNESS: Yeah. I mean, 17 there's transmission electron microscopy. 18 I mean, with all due respect to Dick 19 Swanson, who wrote this letter, I know 20 others reviewed there was electron 21 microscopy in the early 1970s. 22 It wasn't -- the industry didn't 23 want to use it, but there was sensitive 24 methods that certainly could, in the words 25 of this, detect -- determine asbestos in</p>

<p style="text-align: right;">Page 254</p> <p>1 talc. And there was transmission -- yeah, 2 so I would disagree. And that -- 3 BY MR. EWALD: 4 Q. Right. And -- go ahead. 5 A. Keep on -- please, keep on going. 6 Q. Just to be clear, though, that 7 disagreement is based on what you have learned, 8 basically, self-taught over the last 850 hours 9 in connection with your report in this case, 10 fair? 11 MS. O'DELL: Object to the form. 12 THE WITNESS: I mean, I had the 13 transmission electron microscopy -- 14 microscope next to me, I mean, in the 15 1970s when was in college. So it's not 16 entirely true that I didn't know about 17 transmission electron microscopy. 18 But, you know, as far as -- and I'm 19 not there at the agency in '86. 20 Self-taught is a little -- 21 MS. O'DELL: Pejorative? 22 THE WITNESS: Thank you, Counsel. 23 BY MR. EWALD: 24 Q. I'm being descriptive. 25 A. I know. I don't think he meant it</p>	<p style="text-align: right;">Page 256</p> <p>1 BY MR. EWALD: 2 Q. I'm asking the questions, and I 3 think you know that. 4 A. Whatever. But do you know the 5 answer to my question? 6 The reason there was controversy 7 was that the industry didn't want to use the 8 most sensitive methods, and they resisted it. 9 Q. Okay. 10 A. Please go on -- on this -- please 11 go on on this document. 12 Q. So I also want to ask you a 13 question. 14 In your -- would you agree with me 15 that the vast majority of incidence where there 16 is supposedly asbestos found in J&amp;J's talc as 17 reported in your expert report are from the 18 1970s; would you agree with that? 19 MS. O'DELL: Object to the form. 20 THE WITNESS: Well, I -- I have a 21 pretty detailed list. I'm happy to pull 22 that up. You know what, let me pull that 23 up in order to answer that question. I 24 have a list of everything that is cited in 25 every test.</p>
<p style="text-align: right;">Page 255</p> <p>1 that way. I actually think, you know, 2 self-learning is a pretty honorable sport; and 3 I'll take it any day. 4 Transmission electron microscopy 5 was available. 6 Q. Okay. And you talk about 7 transmission electron microscopy being 8 available. But they're not only talking about 9 sensitivity here, right? 10 They're talking about how the 11 analytical procedures were not fully developed 12 and that most of the analytical work was 13 conducted without scientific agreement as to 14 which methods were well-suited by 15 identification of asbestiform minerals in talc. 16 And have you conducted any 17 investigation into the adequacy of the 18 scientific test methods available in the early 19 1970s to identify talc? 20 A. Why do you think -- 21 MS. O'DELL: Object to the form. 22 THE WITNESS: Why do you think -- 23 why do you think -- why do you think there 24 was that controversy, sir? 25</p>	<p style="text-align: right;">Page 257</p> <p>1 Could you -- could you do me a 2 favor? Could I have my laboratory -- my 3 notebook? 4 Thank you. 5 Sir, I have a notebook. What was 6 your -- I have a notebook that is divided 7 between the '60s to '70s the '80s to '90s 8 and 2000. I'm happy to give you the 9 number of things that I cite in each 10 decade, right -- 11 BY MR. EWALD: 12 Q. Sir -- 13 A. -- that are here. You know, I mean 14 it's -- we can all count. I think you're 15 right. There's certainly enough positive tests 16 in the '70s that should have resolved this. 17 Q. Okay. So let's go on the -- the 18 assessment proves to be correct -- well, 19 actually, hold on. 20 So the FDA says, "Consequently, FDA 21 considered all analytical results to be of 22 questionable reliability." 23 I take it you disagree with the FDA 24 on this as well and you -- 25 A. Give me just --</p>



<p style="text-align: right;">Page 258</p> <p>1 Q. You --</p> <p>2 A. Just read the whole letter.</p> <p>3 Q. Uh, uh, uh, uh. I'm asking the</p> <p>4 questions here. Doctor I'm asking the</p> <p>5 questions here. Counsel for you is welcome to</p> <p>6 ask you about other parts of the document. We</p> <p>7 might get there too. I'm asking you a question</p> <p>8 about one sentence.</p> <p>9 I want you to answer that question,</p> <p>10 which is: Here the FDA considered all</p> <p>11 analytical results to be a questionable</p> <p>12 reliability from the early 1970s. My question</p> <p>13 is: Do you disagree with the FDA on that?</p> <p>14 A. So in order to answer that</p> <p>15 question, I would ask for sake of completeness,</p> <p>16 that you read the next sentence.</p> <p>17 Q. Fine. "This assessment proved to</p> <p>18 be correct because many questions were</p> <p>19 subsequently raised about results reported in</p> <p>20 the literature (see enclosed copy of National</p> <p>21 Bureau of Standards Special Publication 506</p> <p>22 entitled, "Misidentification of Asbestos in</p> <p>23 Talc"). Because of the questionable nature of</p> <p>24 the analytical results, the agency was not able</p> <p>25 to assess reliably the levels of asbestiform</p>	<p style="text-align: right;">Page 260</p> <p>1 A. Well, you're missing my point, sir.</p> <p>2 And I -- I do disagree because the -- the</p> <p>3 question that I asked was who -- who wrote the</p> <p>4 article that FDA is relying.</p> <p>5 Let me answer that, sir, because I</p> <p>6 know you get to ask me the questions; and I'm</p> <p>7 respectful of that, right.</p> <p>8 But FDA is citing an article in</p> <p>9 this, right. It says, "See enclosed copy of</p> <p>10 the National Bureau of Standards Special</p> <p>11 Publication 506 entitled, "Misidentification of</p> <p>12 Asbestos." That's the authority that FDA is</p> <p>13 relying on.</p> <p>14 If you turn to that article and you</p> <p>15 see that it is authored by William H. Ashton.</p> <p>16 So FDA is saying that all this</p> <p>17 testing is screwed up. Very nice it says it's</p> <p>18 the National Bureau of Standards, but this is</p> <p>19 J&amp;J. Somehow Bill Ashton worked his way in to</p> <p>20 be able to write an article that gets -- it</p> <p>21 says National Bureau of Standards, right. But</p> <p>22 this is J&amp;J feeding the FDA that the testing is</p> <p>23 not reliable.</p> <p>24 And if you look at the record,</p> <p>25 right, transmission microscopy could have been</p>
<p style="text-align: right;">Page 259</p> <p>1 minerals in cosmetic talc then in the</p> <p>2 marketplace."</p> <p>3 A. Thank you. I appreciate that very</p> <p>4 much. Again, you get to ask the question, but</p> <p>5 here's the rhetorical question: Who do you</p> <p>6 think wrote that article that's referenced that</p> <p>7 FDA is relying on?</p> <p>8 Q. So, Doctor, my question to you is:</p> <p>9 The FDA here is questioning the reliability --</p> <p>10 A. Yep.</p> <p>11 Q. -- of the test results in the 1970s</p> <p>12 on the --</p> <p>13 A. Yep.</p> <p>14 Q. -- testing of -- sir, you know I'm</p> <p>15 in the middle of a question. Please let me</p> <p>16 finish.</p> <p>17 A. Of course.</p> <p>18 Q. Here the FDA is questioning the</p> <p>19 reliability of test results for the presence of</p> <p>20 asbestos in talc in the 1970s based on</p> <p>21 questions about the reliability of the</p> <p>22 analytical procedures.</p> <p>23 My question is: Do you disagree</p> <p>24 with the FDA on their assessment of the 1970s</p> <p>25 talc testing for asbestos?</p>	<p style="text-align: right;">Page 261</p> <p>1 used. This could have all been settled back</p> <p>2 then, but the industry didn't want it because</p> <p>3 it was picking up asbestos.</p> <p>4 Q. Do you have any basis to question</p> <p>5 the mineralogical and microscopic capabilities</p> <p>6 of Dr. Ashton during this time period other</p> <p>7 than the fact he is a J&amp;J employee?</p> <p>8 MS. O'DELL: Object to the form.</p> <p>9 THE WITNESS: I -- I don't want</p> <p>10 to -- I didn't know Dr. Ashton. I've</p> <p>11 never met Dr. Ashton.</p> <p>12 You know, you -- you feel when you</p> <p>13 read, you know, somebody's historical --</p> <p>14 the documents, you feel like you get a</p> <p>15 sense of that person. I don't want to</p> <p>16 cast any aspersions on the clear</p> <p>17 Bill Ashton.</p> <p>18 BY MR. EWALD:</p> <p>19 Q. Let me ask you --</p> <p>20 A. Let me -- let me finish the answer.</p> <p>21 Q. Sure.</p> <p>22 A. Let me finish the answer to my</p> <p>23 question.</p> <p>24 It is inconceivable, okay, that --</p> <p>25 let me put it this way: It was masterful,</p>

<p style="text-align: right;">Page 262</p> <p>1 right. I mean, this was -- I mean, the --</p> <p>2 what -- substitute any word you want: Scheme,</p> <p>3 story, narrative, that got Bill, right.</p> <p>4 Turn to the -- if you turn to the</p> <p>5 next page of this letter for completeness,</p> <p>6 right, and you read the second paragraph,</p> <p>7 right, it says --</p> <p>8 Q. I'm sorry. We are not --</p> <p>9 A. No. I get to answer my question.</p> <p>10 I get to finish the answer to my question,</p> <p>11 please.</p> <p>12 Q. Go ahead. Read the whole damn</p> <p>13 thing. Go ahead.</p> <p>14 A. It says, "After FDA took these</p> <p>15 actions many cosmetic manufacturers began to</p> <p>16 analyze their talc for asbestiform minerals as</p> <p>17 part of their quality control programs, and</p> <p>18 talc suppliers began to sell higher purity</p> <p>19 talcs to the cosmetic industry. By 1976,</p> <p>20 asbestos analytical methodology was</p> <p>21 sufficiently developed," right, "that</p> <p>22 the...CTFA could issue a specification (copy</p> <p>23 enclosed)" -- right, this is J4-1 -- "for</p> <p>24 cosmetic talc. This specification required</p> <p>25 that such talc be free of fibrous amphibole."</p>	<p style="text-align: right;">Page 264</p> <p>1 MS. O'DELL: Object to the form.</p> <p>2 THE WITNESS: If you look -- go</p> <p>3 further in this document, go into the</p> <p>4 background documents, okay, look at memos</p> <p>5 to Gary Flamm -- I'm sure you've seen</p> <p>6 them -- where Flamm says there is a</p> <p>7 consensus -- let me -- let me get it to</p> <p>8 get the exact words.</p> <p>9 Flamm is saying at FDA the fact --</p> <p>10 it's a general consensus the current talc</p> <p>11 mines are virtually free of asbestos.</p> <p>12 Offending mines should -- have gradually</p> <p>13 been abandoned, you know, and that any</p> <p>14 residual silicates in talc are so -- are</p> <p>15 finely and smoothly ground. So there's no</p> <p>16 issue.</p> <p>17 Did you close the mines?</p> <p>18 You ground the stuff up to such a</p> <p>19 level that it was all -- it was impossible</p> <p>20 to clearly see it. Bill Ashton, did he</p> <p>21 know that?</p> <p>22 Of course he had to know that. I</p> <p>23 don't know that he knew that, but anyone</p> <p>24 who knows -- if you look at the specs and</p> <p>25 you look at the size of asbestos fibers,</p>
<p style="text-align: right;">Page 263</p> <p>1 That was the requirement. "Asbestos in the</p> <p>2 form of asbestiform tremolite using a CTFA</p> <p>3 method of analysis that is capable of detecting</p> <p>4 0.5 percent of amphibole asbestos. This</p> <p>5 specification contributed to the continued</p> <p>6 improvement of the cosmetic talc quality."</p> <p>7 You never had a positive test under</p> <p>8 this and that protects. But the fallacy is</p> <p>9 that if there's 5.5 percent -- .5 percent, you</p> <p>10 scratch your head. How did Dick Swanson, whose</p> <p>11 name was Dr. Doom -- that was his nickname if</p> <p>12 you want to know the history, right -- how did</p> <p>13 FDA -- how -- if there's .5 percent of</p> <p>14 amphibole asbestos, how do you go and say there</p> <p>15 is no asbestos?</p> <p>16 There was never a reliable standard</p> <p>17 put in place to say there was no asbestos.</p> <p>18 There's been asbestos in his product since in</p> <p>19 the 1970s, and it's continued; and it's all</p> <p>20 been masked.</p> <p>21 Q. Okay. And so to summarize, you</p> <p>22 feel like with your background, you are better</p> <p>23 situated on assessing the reliability of the</p> <p>24 analytical methods for testing talc, the</p> <p>25 presence of asbestos, than Bill Ashton, fair?</p>	<p style="text-align: right;">Page 265</p> <p>1 you're grinding it up to 10 microns,</p> <p>2 you're going to be grinding this stuff --</p> <p>3 this was all -- this was all premised on</p> <p>4 the fact that asbestos wasn't in there;</p> <p>5 and, in fact, it was just masked.</p> <p>6 BY MR. EWALD:</p> <p>7 Q. Are you done now?</p> <p>8 A. You have my answer. Thank you.</p> <p>9 Q. Sure.</p> <p>10 THE WITNESS: Could I ask for a</p> <p>11 time check, please.</p> <p>12 MS. O'DELL: Yes. We've been on</p> <p>13 the record for about an hour and 15</p> <p>14 minutes. So why don't we -- do you want</p> <p>15 to take a short break?</p> <p>16 THE WITNESS: No. I can keep on</p> <p>17 going.</p> <p>18 MS. O'DELL: Suzanne, could you</p> <p>19 give us a time check, please?</p> <p>20 (Discussion held off the record.)</p> <p>21 MR. EWALD: Let's take a break, and</p> <p>22 then finish up the last hour and 15.</p> <p>23 THE WITNESS: Thank you, sir, very</p> <p>24 much. I appreciate it.</p> <p>25 (Whereupon, a break was taken.)</p>

<p style="text-align: right;">Page 266</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Okay. Doctor, when we were about</p> <p>3 to come back on the record, you indicated that</p> <p>4 there was something that you wanted to clarify.</p> <p>5 Go ahead.</p> <p>6 A. Okay. I'd just clarify, there's</p> <p>7 a -- we need to get you -- there's a very minor</p> <p>8 errata sheet. There's -- I think I spelled the</p> <p>9 word "fibers" wrong in the report, and there's</p> <p>10 some missed Bates numbers. There may be some</p> <p>11 on certain cites. So I'm just -- for the sake</p> <p>12 of completeness.</p> <p>13 And I also want to make sure</p> <p>14 that -- I think I misspoke. Obviously there</p> <p>15 was the petition that got responded to in '86,</p> <p>16 but then there was two petitions that got</p> <p>17 responded to -- I think I was clear -- it was</p> <p>18 in the '94 and then in 2008, both got responded</p> <p>19 to in 2014, as I think I cited in the letter;</p> <p>20 but I may have misspoke. And I may have said</p> <p>21 there was one, and we were actually talking</p> <p>22 about a total of three petitions, I think,</p> <p>23 historically. I just wanted to make sure the</p> <p>24 record was clear. Thanks, sir.</p> <p>25 Q. Of course. And not that it really</p>	<p style="text-align: right;">Page 268</p> <p>1 it in. It's too small for me to see right now.</p> <p>2 Sir, I just need to get it put in the chat.</p> <p>3 Thank you very much. I appreciate</p> <p>4 that.</p> <p>5 Let me just see. 17147 coming up.</p> <p>6 Got it. I can read it; and yes, I have it,</p> <p>7 sir.</p> <p>8 Q. And this is talking -- this is a</p> <p>9 Johnson &amp; Johnson memo dated February 23rd,</p> <p>10 1978, to Windsor Minerals, Mr. Miller,</p> <p>11 president.</p> <p>12 It says, "As you know, Windsor</p> <p>13 Minerals and the baby products company have</p> <p>14 already authorized the documentation of a</p> <p>15 no-detectable asbestos requirement in the</p> <p>16 Windsor 66 Talc Material Specification. In</p> <p>17 this regard, the testing requirement is solely</p> <p>18 for fibrous amphibole by the CTFA method J4-1</p> <p>19 as intended to make the specification wholly</p> <p>20 consistent with the CTFA standard for cosmetic</p> <p>21 grade talc. However, we need to recognize that</p> <p>22 Windsor Minerals and Johnson &amp; Johnson have</p> <p>23 exercised more extensive controls and testing</p> <p>24 in the past than just meeting the J4-1</p> <p>25 requirement. Furthermore, we intend continuing</p>
<p style="text-align: right;">Page 267</p> <p>1 matters that much, but I completely agree on</p> <p>2 that point that there are three petitions that</p> <p>3 we've talked about. And I think it was clear</p> <p>4 in the record, but extra clear now.</p> <p>5 MS. O'DELL: John, just to follow</p> <p>6 up on what Dr. Kessler said, I'm putting</p> <p>7 in the chat a short list of just typos and</p> <p>8 other, like, transposed numbers,</p> <p>9 et cetera, that are composed as errata for</p> <p>10 his report. And so you have it there in</p> <p>11 the chat for your review.</p> <p>12 BY MR. EWALD:</p> <p>13 Q. Okay. Doctor, I want to jump</p> <p>14 around a little bit here the last hour or so,</p> <p>15 and I want to return to this question of what</p> <p>16 testing J&amp;J did historically. Don't worry. We</p> <p>17 will get to your slide presentation, but first</p> <p>18 I want to show you a couple of documents.</p> <p>19 MR. EWALD: Jake, can you please</p> <p>20 drop in DX 17147.</p> <p>21 MR. KEESTER: Yep.</p> <p>22 BY MR. EWALD:</p> <p>23 Q. And, Doctor, just let me know when</p> <p>24 you have a chance to look on the screen --</p> <p>25 A. Do me a favor. Can you please put</p>	<p style="text-align: right;">Page 269</p> <p>1 to surpass the industry standard of testing as</p> <p>2 reflected by CTFA's J4-1.</p> <p>3 "During the July 15, 1977, meeting</p> <p>4 in your office, we had agreed to the need of</p> <p>5 documenting the entire audit protocol, which</p> <p>6 has been your standard operating policy and</p> <p>7 procedure since August 1973 and it will be</p> <p>8 continued to be practiced by Windsor Minerals</p> <p>9 for Windsor 66 Talc."</p> <p>10 Did I read that correctly?</p> <p>11 A. You did.</p> <p>12 Q. Is this a document you've seen</p> <p>13 before?</p> <p>14 A. I believe so. I mean, I believe</p> <p>15 I've seen this before.</p> <p>16 Q. Okay. So it talks about for sample</p> <p>17 type ground or TM7024 --</p> <p>18 A. Whoa, whoa. Wait a second. I want</p> <p>19 to make sure where you have me now.</p> <p>20 Q. Top of the second page.</p> <p>21 A. Yeah. I'm not on the second page.</p> <p>22 That's my problem. Hold on a second. Let me</p> <p>23 get there. Yep.</p> <p>24 Q. Okay. Ground or TM7024 biweekly</p> <p>25 composite samples by Windsor flash-dried talc</p>

<p style="text-align: right;">Page 270</p> <p>1 CTFA J4-1, TM7019, positive samples by J&amp;J.  2 And it includes here in the different  3 characteristics tests 7019.  4 You were complaining -- or you were  5 noting that J4-1 does not apply to chrysotile.  6 Are you, first, sir, aware that  7 chrysotile is a form of serpentine?  8 A. Sure.  9 Q. And this talks about a test  10 conducted by J&amp;J TM7019, correct?  11 A. I'm sorry. You slurred. I didn't  12 hear that clearly at the end.  13 Q. This testing method, TM7019, that's  14 talked about here for the serpentine form is  15 discussed above for flash-dried talc, weekly  16 composite samples by J&amp;J, correct?  17 A. I see that well.  18 Q. Okay. And so, I guess, how does  19 this comport with your opinion about the lack  20 of TEM testing by J&amp;J in the '70s?  21 A. Well, you certainly -- a couple of  22 things. One, I mean, it's not clear to me,  23 actually, who -- I think what you said is I'm  24 not -- it's not clear to me who did the TEM for  25 J&amp;J. I'm not sure that they consistently did</p>	<p style="text-align: right;">Page 272</p> <p>1 that it should be clarified exactly who  2 was doing TEM at the time.  3 We know from -- I know documents  4 that TEM was generally -- certainly, Rio  5 Tinto and Luzenac, the documents say that  6 that TEM was only beginning in the really  7 from Rio Tinto, Luzenac, Cyprus they  8 started in the late 1980s.  9 I -- I am aware of these two  10 policies TM7024 and 7019. It's not clear  11 to me -- when you say Johnson &amp; Johnson  12 did it, it's not clear who the Johnson &amp;  13 Johnson actually did it and whether  14 McCrone did it, right, or J&amp;J.  15 I am saying is that this was done  16 in a way that -- really you can use  17 whatever word you want -- made the test  18 very unsensitive. Again, it masked the  19 presence of asbestos, right. If you have  20 to show five, right, if you're detecting  21 one or two or three -- and I can take you  22 through examples where they detected  23 asbestos, but they didn't count it.  24 That's absurd, right.  25 And you didn't need to have that</p>
<p style="text-align: right;">Page 271</p> <p>1 it in-house. Okay. I -- I think McCrone may  2 have done that, but, again, I'm open to  3 whatever the facts are.  4 Number 2, if you look at Rio Tinto,  5 the TEM really only got accepted by the Rio  6 Tinto, Luzenac by the late 1980s and 1990s. I  7 see this in there. This was the weekly and  8 biweekly composites, right.  9 But understand, there was the -- it  10 was the five-fiber rule to this, which made  11 this, which you see in analysis by McCrone  12 where they find fibers and they throw it --  13 they don't -- your word "detectable," they said  14 it's only detectable if there's five fibers.  15 If you detect one, it's not detectable.  16 So this was all -- I mean, there  17 wasn't serious TEM with that five-fiber rule.  18 Q. Okay. So first of all, I want to  19 understand.  20 Are you saying that if J&amp;J wasn't  21 doing the TEM testing itself but was having  22 someone else do it, that somehow is less valid?  23 A. No.  24 MS. O'DELL: Object to the form.  25 THE WITNESS: No. I just figure</p>	<p style="text-align: right;">Page 273</p> <p>1 five rule for statistical methods. You  2 know, that says that, and he publishes  3 that was -- that wasn't necessary for  4 statistical methodology, right. So you  5 took a test that was very -- that was  6 sensitive, and you made it insensitive by  7 the rule.  8 BY MR. EWALD:  9 Q. First of all, are you now  10 recognizing that Johnson &amp; Johnson did TEM  11 testing in the 1970s?  12 A. On biweekly composite. I'm -- I'm  13 aware of this. I'm not sure Johnson &amp; Johnson  14 did it. There's a sheet -- there is a in the  15 analytical that says transmission electronic  16 microscopy was begun and becoming more  17 generally accepted in the 1980s.  18 That's what's -- certainly, that's  19 the -- the Rio Tinto and Luzenac and Cyprus  20 companies generally viewed TEM as becoming more  21 generally used in their batch-by-batch analysis  22 and routinely used beginning more in the 1980s,  23 right. That's what the record shows.  24 There was this TEM that was used.  25 I'm not sure exactly who did it; but from the</p>

<p style="text-align: right;">Page 274</p> <p>1 protocols, it had this five-fiber rule. And it</p> <p>2 certainly -- it didn't seem -- the mining</p> <p>3 companies didn't seem to be -- the producers</p> <p>4 didn't seem to be using it to assure the safety</p> <p>5 of what they were giving J&amp;J. This was done on</p> <p>6 these big silos and these composites material.</p> <p>7 That's what I know.</p> <p>8 Q. Okay. But you -- but you -- so</p> <p>9 your point about -- you do realize that J&amp;J is</p> <p>10 a completely different entity than Luzenac or</p> <p>11 IMERYS; you recognize that, right?</p> <p>12 A. Certainly, sir. But under the</p> <p>13 Federal Food Drug and Cosmetic Act, who's</p> <p>14 responsible for the production of the powder?</p> <p>15 J&amp;J. J&amp;J audited the companies.</p> <p>16 J&amp;J found critical violations in companies like</p> <p>17 RW -- RJ Lee. You raise that. J&amp;J knew what</p> <p>18 was going on.</p> <p>19 Q. But my point is that you are</p> <p>20 somehow criticizing J&amp;J for conducting its own</p> <p>21 TEM work?</p> <p>22 MS. O'DELL: Object.</p> <p>23 THE WITNESS: No. We don't know</p> <p>24 they were doing their own.</p> <p>25 Who is this doing this for -- I</p>	<p style="text-align: right;">Page 276</p> <p>1 you look at these policies, you only count if</p> <p>2 there's five fibers.</p> <p>3 I mean, I'm giving J&amp;J no credit</p> <p>4 for putting in place a policy that obscures the</p> <p>5 presence of asbestos.</p> <p>6 Q. And so -- and you're saying that in</p> <p>7 your view, based on your review of this case,</p> <p>8 that there was no basis to have the five-fiber</p> <p>9 detection limit.</p> <p>10 That's your opinion?</p> <p>11 A. What I've read from -- in Millette</p> <p>12 was to, again -- if you asked, again, what a</p> <p>13 word means, right, whether something is</p> <p>14 detectable, if you -- no detectable -- if you</p> <p>15 go back to the first page of this, right, there</p> <p>16 was no detectable asbestos.</p> <p>17 To me, if you detect an asbestos</p> <p>18 fiber, right, and you see it and you can</p> <p>19 confirm it, that's detected. To make a rule</p> <p>20 that says it has to be five, somebody came up</p> <p>21 with a theory, well, we want to probably -- we</p> <p>22 want to avoid a background and a statistical</p> <p>23 methodology on -- so it had to be five.</p> <p>24 What Millette says is there was no</p> <p>25 basis for that, and it didn't need to be made.</p>
<p style="text-align: right;">Page 275</p> <p>1 mean, I'm not aware that this was done</p> <p>2 in-house in J&amp;J. I can't figure out</p> <p>3 whether this was done consistently for</p> <p>4 decades by J&amp;J. I don't know that.</p> <p>5 BY MR. EWALD:</p> <p>6 Q. I think --</p> <p>7 A. I --</p> <p>8 Q. -- for documents?</p> <p>9 MS. O'DELL: I'm sorry, John. I</p> <p>10 don't think he was finished.</p> <p>11 BY MR. EWALD:</p> <p>12 Q. Finish please.</p> <p>13 A. Yes. I'm trying to sort that out</p> <p>14 because I've seen this. I've see a lot of</p> <p>15 McCrone documents on TEM.</p> <p>16 I think it was McCrone who did this</p> <p>17 for J&amp;J. Nevertheless, I mean, I'm not</p> <p>18 disagreeing. I don't see quite records over</p> <p>19 the 50 years of -- of this. I don't see that</p> <p>20 database.</p> <p>21 I think many of these results</p> <p>22 were -- I mean, if I'm correct -- were held by</p> <p>23 McCrone and Bain from what I can tell, but I do</p> <p>24 know that when TEM was used, certainly by the</p> <p>25 McCrone and certainly under these policies --</p>	<p style="text-align: right;">Page 277</p> <p>1 And to say you detect it, you don't need five</p> <p>2 to detect it. You have a way of assuring</p> <p>3 background noise through blinds.</p> <p>4 Q. All right. And so is this also</p> <p>5 part of a conspiracy by Johnson &amp; Johnson to</p> <p>6 institute the five-fiber rule?</p> <p>7 MS. O'DELL: Objection. Form.</p> <p>8 THE WITNESS: That -- that's</p> <p>9 between you, your client, and their gods.</p> <p>10 BY MR. EWALD:</p> <p>11 Q. Do you -- is it your -- you've got</p> <p>12 evidence, Doctor, that the five-fiber rule is</p> <p>13 something that J&amp;J created?</p> <p>14 MS. O'DELL: Object to the form.</p> <p>15 THE WITNESS: I can say -- saying</p> <p>16 that five fibers had to be detected,</p> <p>17 you've got to have five to detect asbestos</p> <p>18 and asbestos fiber doesn't make any sense.</p> <p>19 Millette said they got rid of it, right.</p> <p>20 So you didn't need that.</p> <p>21 Again, this is no detectable</p> <p>22 asbestos. I mean, come on. You're an --</p> <p>23 you're an excellent lawyer. You know that</p> <p>24 that word "detectable" is in there for a</p> <p>25 reason. It's in there to obscure it,</p>



<p style="text-align: right;">Page 278</p> <p>1 right. If somebody came up with a</p> <p>2 definition, we'll decide what is</p> <p>3 detectable. That's the game that's being</p> <p>4 played.</p> <p>5 BY MR. EWALD:</p> <p>6 Q. Okay. So you talked a lot about</p> <p>7 Millette.</p> <p>8 What do know about Millette?</p> <p>9 A. Millette was a microscopist.</p> <p>10 Q. Okay. What else do you know about</p> <p>11 him?</p> <p>12 A. I mean, he's published in this</p> <p>13 area, and I've read some of his articles; and</p> <p>14 he discusses the five-fiber rule.</p> <p>15 Q. And does it -- in your opinion, is,</p> <p>16 based on your study over the last year, is</p> <p>17 Dr. Millette a well-respected microscopist?</p> <p>18 A. Sure. I -- I was using that term,</p> <p>19 you know, in a gentlemanly way. I don't</p> <p>20 know -- I mean, I'll put him in -- I have no</p> <p>21 reason to question his wonderful nature.</p> <p>22 Q. Is he world class like Dr. Longo?</p> <p>23 What do you think?</p> <p>24 MS. O'DELL: Object to the form.</p> <p>25 THE WITNESS: I take -- I take the</p>	<p style="text-align: right;">Page 280</p> <p>1 (Whereupon, Exhibit 17, Article</p> <p>2 published in "The Microscope" in Volume 38</p> <p>3 Fourth Quarter 1990, was marked for</p> <p>4 identification.)</p> <p>5 MR. EWALD: And Kevin -- Kevin --</p> <p>6 Jake, sorry. Can you please drop it in</p> <p>7 the chat?</p> <p>8 MR. KEESTER: I can, yes.</p> <p>9 What's the -- sorry.</p> <p>10 MR. EWALD: It is DX-19666.</p> <p>11 MR. KEESTER: Sending now.</p> <p>12 MR. EWALD: Thank you.</p> <p>13 BY MR. EWALD:</p> <p>14 Q. Doctor, let me know when you have</p> <p>15 it in front of you.</p> <p>16 A. Yeah. I'm just doing it.</p> <p>17 I do. My copy is a little</p> <p>18 different.</p> <p>19 Where's that paragraph?</p> <p>20 Q. Yeah. So first of all, this is</p> <p>21 published in "The Microscope" in 1990, correct?</p> <p>22 A. Correct. I have it -- mine's</p> <p>23 formatted a little different from the one I</p> <p>24 have, yes.</p> <p>25 Q. So it's called, "A Standard TEM</p>
<p style="text-align: right;">Page 279</p> <p>1 lateness of the hour, and I appreciate the</p> <p>2 sense of humor.</p> <p>3 BY MR. EWALD:</p> <p>4 Q. Well, is it a joke?</p> <p>5 Which way is it silly?</p> <p>6 Silly because Dr. Longo --</p> <p>7 A. No. I think from what I can tell</p> <p>8 Millette was very serious and is in the</p> <p>9 category of Longo, and I'm not having any -- I</p> <p>10 have no problems. I think Millette contributed</p> <p>11 to the field from everything I saw. I think he</p> <p>12 is in that category.</p> <p>13 Q. Okay. And do you happen to know</p> <p>14 what -- you talked about TM7024 in that last</p> <p>15 document, right?</p> <p>16 That's the J&amp;J's TEM method?</p> <p>17 A. Yes.</p> <p>18 Q. In all of your research, did you</p> <p>19 figure out where J&amp;J got that TM7024 from?</p> <p>20 A. He got it from Millette, I believe.</p> <p>21 Q. Okay. So Millette --</p> <p>22 MR. EWALD: Mark this as -- we'll</p> <p>23 mark this as Exhibit 17. It's the</p> <p>24 Millette 1990 article.</p> <p>25</p>	<p style="text-align: right;">Page 281</p> <p>1 Procedure for Identification and Quantitation</p> <p>2 of Asbestiform Minerals in Talc," correct?</p> <p>3 A. Correct.</p> <p>4 Q. And amongst the co-authors is</p> <p>5 James R. Millette, right?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. And so if you scroll down</p> <p>8 under "standard operating procedure" --</p> <p>9 MS. O'DELL: Doctor -- excuse me.</p> <p>10 Doctor --</p> <p>11 THE WITNESS: What page are you on?</p> <p>12 BY MR. EWALD:</p> <p>13 Q. I'm on page 10 carrying over to 11?</p> <p>14 A. Give me -- give me the page number</p> <p>15 on the bottom.</p> <p>16 Q. 463.</p> <p>17 A. 463.</p> <p>18 Q. Section 6.</p> <p>19 A. Yeah.</p> <p>20 Q. "Limit of Quantifiable Detection,"</p> <p>21 do you see that?</p> <p>22 A. Right.</p> <p>23 MS. O'DELL: And if you need to</p> <p>24 take time to read the article, feel free</p> <p>25 to do so.</p>

<p style="text-align: right;">Page 282</p> <p>1 BY MR. EWALD:</p> <p>2 Q. It states, "The detection of five</p> <p>3 or more asbestos minerals of one variety in an</p> <p>4 analysis constitutes a quantifiable level of</p> <p>5 detection." Do you see that?</p> <p>6 A. Correct.</p> <p>7 Q. And is that the same standard used</p> <p>8 by J&amp;J in the TM7024 method?</p> <p>9 A. Well, it's really -- this is 1990,</p> <p>10 right.</p> <p>11 Q. Right.</p> <p>12 A. You're citing to a 1970 method.</p> <p>13 Q. Are you saying that the science --</p> <p>14 well, let's -- let's toggle. Okay. Let's look</p> <p>15 at 230.3 in your report.</p> <p>16 Do you have that one on paper in</p> <p>17 front of you?</p> <p>18 A. What paragraph, sir?</p> <p>19 Q. 230.3. It's on page 102?</p> <p>20 A. 102, thanks. Hold on a second.</p> <p>21 230.3.</p> <p>22 Q. Yep.</p> <p>23 A. And that is -- that year is 2015,</p> <p>24 right?</p> <p>25 Q. Right. It's in 2015. You quote</p>	<p style="text-align: right;">Page 284</p> <p>1 page 50.</p> <p>2 A. 121. Okay. Thank you.</p> <p>3 Q. And this paragraph refers to the</p> <p>4 Dutch Consumer Organization.</p> <p>5 THE WITNESS: Can I have my</p> <p>6 paragraph 121, please, in the book?</p> <p>7 Yes, sir.</p> <p>8 BY MR. EWALD:</p> <p>9 Q. All right. And does 121, the</p> <p>10 paragraph, represent the complete story on what</p> <p>11 happened with the analysis of the talc at issue</p> <p>12 here?</p> <p>13 A. I'm pulling -- I'm pulling it up.</p> <p>14 The complete story? I'm happy to have you</p> <p>15 expand.</p> <p>16 Q. Well, do you -- do you know</p> <p>17 anything more than what's reflected there on</p> <p>18 paragraph 121?</p> <p>19 A. I know -- I know what I see in the</p> <p>20 Johnson &amp; Johnson Dutch file by Mr. Homan.</p> <p>21 Q. All right. Let me show you --</p> <p>22 MR. EWALD: Jake, can you drop</p> <p>23 D-7070 into the chat, please.</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 283</p> <p>1 Dr. Millette saying, "For lack of better</p> <p>2 statistical information at the time in 1990,</p> <p>3 the publication stated rule of thumb of the</p> <p>4 detection of five or more asbestiform minerals</p> <p>5 of one variety in an analysis constituted a</p> <p>6 quantifiable level of detection. Subsequent</p> <p>7 method of development in the area of TEM</p> <p>8 analysis for asbestos has shown that a</p> <p>9 detection of less than five fibers in the</p> <p>10 sample can provide a statistically valid</p> <p>11 result."</p> <p>12 So are you suggesting that it was a</p> <p>13 method by Johnson &amp; Johnson to mask asbestos</p> <p>14 when it was using this method in the 1970s,</p> <p>15 '80s, '90s?</p> <p>16 A. It did as a consequence of that.</p> <p>17 Q. And you're basing that on your</p> <p>18 expertise in mineralogy and microscopy?</p> <p>19 A. No. I'm basing that on your</p> <p>20 ability to count.</p> <p>21 Q. Okay. Okay. I'll take that.</p> <p>22 Now, let's go to something else.</p> <p>23 Let's go to 121 in your report, page 50.</p> <p>24 A. 121?</p> <p>25 Q. Yep. Paragraph number -- or</p>	<p style="text-align: right;">Page 285</p> <p>1 (Whereupon, Exhibit 18, Johnson &amp;</p> <p>2 Johnson document with the subject:</p> <p>3 "Allegation made by Dutch Consumer</p> <p>4 Organization of Asbestos in our</p> <p>5 Overseas Talc - Project No. 0936.00,"</p> <p>6 dated September 20, 1973, was marked for</p> <p>7 identification.)</p> <p>8 BY MR. EWALD:</p> <p>9 Q. And when you get a chance, Doctor,</p> <p>10 take a look at this and see if this is a</p> <p>11 document you've seen before.</p> <p>12 A. Let me just get it out of chat and</p> <p>13 see if I remember.</p> <p>14 Q. Sure.</p> <p>15 A. 7077?</p> <p>16 Q. Well, this one is DX -- yeah, 7070.</p> <p>17 A. Yeah. Thanks. Give me a second.</p> <p>18 I need to look at this a second.</p> <p>19 Q. Sure.</p> <p>20 A. I -- I got it. Let me just make it</p> <p>21 a little bigger.</p> <p>22 Q. So does this document look</p> <p>23 familiar?</p> <p>24 A. I have to review it. I -- at this</p> <p>25 hour my brain is not computing fully. I'd --</p>

<p style="text-align: right;">Page 286</p> <p>1 I'd want to look at the whole thing. I think</p> <p>2 so. I think I've seen this, but I -- I'd have</p> <p>3 to -- I don't -- I'd have to -- I'd have to</p> <p>4 read the whole thing.</p> <p>5 MS. O'DELL: So if you need a</p> <p>6 minute, Doctor, take it.</p> <p>7 THE WITNESS: Okay. Thanks. Hold</p> <p>8 on a second.</p> <p>9 Is it the use of the standing</p> <p>10 electron microscopy issue?</p> <p>11 BY MR. EWALD:</p> <p>12 Q. Well, it depends on --</p> <p>13 A. I'm sorry?</p> <p>14 Q. I'll ask you questions about it.</p> <p>15 But finish reading the document, and then I'll</p> <p>16 ask questions.</p> <p>17 A. Well, again, it's going to take me</p> <p>18 about five, ten minutes to read this. I think</p> <p>19 this is the SEM issue, right?</p> <p>20 Q. That's the SEM issue, yes?</p> <p>21 A. Right. Feel free to ask me the SEM</p> <p>22 question, and I'll respond.</p> <p>23 Q. Well, I also have a question about</p> <p>24 the definition, so just read it.</p> <p>25 A. Okay. Well...</p>	<p style="text-align: right;">Page 288</p> <p>1 definition, they might trace asbestos again and</p> <p>2 publicize the results."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes, sir.</p> <p>5 Q. Okay.</p> <p>6 A. I think --</p> <p>7 Q. And by the way --</p> <p>8 A. I -- I'm sorry.</p> <p>9 Q. Go ahead.</p> <p>10 A. I see those words in the underlying</p> <p>11 document, yes.</p> <p>12 Q. All right. Okay.</p> <p>13 And so by the way, I'm not sure how</p> <p>14 much you paid attention to this. But 1.59</p> <p>15 percent of asbestos, that's a pretty large</p> <p>16 number relative to what, for example, Dr. Longo</p> <p>17 was finding, right?</p> <p>18 MS. O'DELL: Object to the form.</p> <p>19 THE WITNESS: Yeah. I'm not --</p> <p>20 I'm -- I'm not going to do math right</p> <p>21 here, I mean, in a deposition. I'm not</p> <p>22 prepared to answer -- I mean, I don't have</p> <p>23 an opinion on that question.</p> <p>24 BY MR. EWALD:</p> <p>25 Q. Okay. So do you have an</p>
<p style="text-align: right;">Page 287</p> <p>1 MS. O'DELL: Take your time.</p> <p>2 THE WITNESS: And this is what</p> <p>3 year?</p> <p>4 This is -- what's the date of this?</p> <p>5 This is '73, right.</p> <p>6 Got it. Thank you.</p> <p>7 Yeah. Do you see he's questioning</p> <p>8 the questioning of the SEM and the</p> <p>9 effectiveness of SEM as a microscopy</p> <p>10 method?</p> <p>11 BY MR. EWALD:</p> <p>12 Q. Well, so let's -- first, let's walk</p> <p>13 through it.</p> <p>14 First, turning to your</p> <p>15 paragraph 121, you refer to an August 27th,</p> <p>16 1973, internal J&amp;J memorandum acknowledged that</p> <p>17 the Dutch Consumer Organization analyzed</p> <p>18 Johnson's Baby Powder and detected asbestos</p> <p>19 content at 1.59 percent.</p> <p>20 "Johnson &amp; Johnson noted that the</p> <p>21 organization's definition of asbestos could</p> <p>22 cause some errors, and at this moment they are</p> <p>23 analyzing our powder again because we remarked</p> <p>24 that our powder was free of asbestos. However,</p> <p>25 when they stick to the same method and</p>	<p style="text-align: right;">Page 289</p> <p>1 understanding, as you sit here today, about the</p> <p>2 average level of asbestos by volume?</p> <p>3 A. No. I --</p> <p>4 Q. Dr. Longo's finding?</p> <p>5 A. No. I --</p> <p>6 MS. O'DELL: Object to the form.</p> <p>7 THE WITNESS: No. What I'm doing</p> <p>8 is -- I don't want -- without the</p> <p>9 laboratory tests that support this, I</p> <p>10 don't want to just comment on the</p> <p>11 1.59 percent. I want to understand</p> <p>12 exactly what the metrics are that are</p> <p>13 being used and understand exactly what the</p> <p>14 Dutch -- this is a J&amp;J representation of</p> <p>15 the Dutch. This is exactly what it said</p> <p>16 here.</p> <p>17 But if you want to get into the</p> <p>18 metrics, let's pull up the underlying</p> <p>19 Dutch study; and then we can understand</p> <p>20 it.</p> <p>21 BY MR. EWALD:</p> <p>22 Q. Well, you didn't apparently feel</p> <p>23 the need to assess its accuracy before putting</p> <p>24 it in your report, correct?</p> <p>25 A. No. I --</p>

<p style="text-align: right;">Page 290</p> <p>1 MS. O'DELL: Object to the form.</p> <p>2 THE WITNESS: So just let me</p> <p>3 read -- what this -- this whole section is</p> <p>4 about, if you go back to the heading,</p> <p>5 right, what -- you didn't assure the</p> <p>6 safety and this is -- these were all</p> <p>7 questions that was raised.</p> <p>8 So I mean, it goes to whether you</p> <p>9 substantiated the safety of the product.</p> <p>10 The responsibility of that falls with J&amp;J.</p> <p>11 Okay.</p> <p>12 BY MR. EWALD:</p> <p>13 Q. Okay. So --</p> <p>14 A. These were questions that were --</p> <p>15 these were questions that were raised. There's</p> <p>16 no question that this Dutch agency raised that</p> <p>17 question, but go ahead, please.</p> <p>18 Q. All right. And so the Dutch agency</p> <p>19 raises the question in August 27, 1973, as is</p> <p>20 reflected in the internal J&amp;J memorandum.</p> <p>21 And then in September 20, 1973, a</p> <p>22 little less than a month later, we have some</p> <p>23 further responses from J&amp;J where they, again,</p> <p>24 talk about your reported 1.59-percent asbestos</p> <p>25 content.</p>	<p style="text-align: right;">Page 292</p> <p>1 asbestos minerals.</p> <p>2 And he goes on to say, "The</p> <p>3 definition of asbestos offered by the Dutch</p> <p>4 Consumer Organization is as follows: All</p> <p>5 needle and/or fibrous parts or composed units,</p> <p>6 consisting of magnesium and silicon."</p> <p>7 That's what he says, right?</p> <p>8 MS. O'DELL: Object to the form.</p> <p>9 Compound.</p> <p>10 THE WITNESS: That's exact --</p> <p>11 that's -- that's what he says.</p> <p>12 BY MR. EWALD:</p> <p>13 Q. Okay. And then he goes on to say,</p> <p>14 "By this definition, if talc or the common</p> <p>15 mineral impurity chlorite (a magnesium</p> <p>16 silicate) appeared to look fibrous by their</p> <p>17 analytical technique (see next section), then</p> <p>18 it would be called asbestos. However, if, for</p> <p>19 example, tremolite and anthophyllite asbestos</p> <p>20 were present in a fibrous form, then by their</p> <p>21 definition, they would not be called asbestos</p> <p>22 since they have elements other than just</p> <p>23 magnesium and silicon. Tremolite is a calcium</p> <p>24 magnesium silicate, and anthophyllite is a</p> <p>25 magnesium iron silicate."</p>
<p style="text-align: right;">Page 291</p> <p>1 "In this report I hope to show that</p> <p>2 their definition of asbestos is incorrect, and</p> <p>3 their analytical method for asbestos</p> <p>4 determination in talc is not specific enough</p> <p>5 and has severe limitations and the talc they</p> <p>6 are using, Italian 0000, has been thoroughly</p> <p>7 analyzed by different scientists in different</p> <p>8 countries and by different methods, and no</p> <p>9 detectable levels of asbestos have been found."</p> <p>10 That's what he says there, right?</p> <p>11 A. That's what he's -- that's what</p> <p>12 he's trying to -- that's the case he's trying</p> <p>13 to make.</p> <p>14 Q. Okay. And he goes on, on page 1</p> <p>15 formally with the memo talking about definition</p> <p>16 of asbestos. And he says, "Talc is normally</p> <p>17 defined simply as a natural hydrous magnesium</p> <p>18 silicate usually occurring in a platy form."</p> <p>19 And he talks about how, "Talc and</p> <p>20 all the asbestos minerals can, however, be</p> <p>21 unambiguously defined by determination of their</p> <p>22 unique chemical structure of each mineral by</p> <p>23 such methods as X-ray diffraction."</p> <p>24 He talks about the unique chemical</p> <p>25 structure of talc as it compares to different</p>	<p style="text-align: right;">Page 293</p> <p>1 Did I read that correctly?</p> <p>2 A. You're correct.</p> <p>3 Q. Do you have any expertise to have</p> <p>4 an opinion one way or the other as to whether</p> <p>5 or not Dr. Rolle is correct here?</p> <p>6 A. Yeah. We -- he's not correct</p> <p>7 because he's not dealing with the biological</p> <p>8 activity of fibers, and he's missing that.</p> <p>9 He's trying to draw distinctions between</p> <p>10 certain fibers and other fibers and not</p> <p>11 recognizing what -- if you want to go back to</p> <p>12 the IWGACP spent both -- their entire</p> <p>13 appendices on was the exactly to say that</p> <p>14 Dr. Rohl was wrong because we should be looking</p> <p>15 at biological activity of fibers as it relates</p> <p>16 to transformative potential. And that's what</p> <p>17 key, and not what's -- let's not do</p> <p>18 definitions. Let's look at the biological</p> <p>19 activity of these fibers.</p> <p>20 So he's wrong in that regard.</p> <p>21 Q. All right. Doctor, is chlorite an</p> <p>22 amphibole?</p> <p>23 A. No. But again, if you have fibrous</p> <p>24 material, you have to analyze that biological</p> <p>25 activity.</p>

<p style="text-align: right;">Page 294</p> <p>1 Q. So should I add to your expert 2 report that it's not only that J&amp;J was 3 misbranded because of not warning of asbestos 4 or nonasbestos form of amphibole, so should we 5 also add fibrous chlorite to that? 6 MS. O'DELL: Object to the form. 7 Misstates his testimony. 8 THE WITNESS: Come on, please. 9 We're -- we're not -- you know, you're -- 10 you want to add it to what? 11 BY MR. EWALD: 12 Q. You said let's -- no. Hold on. 13 Hold on. Hold on. 14 Let's look at 21, I think. No. 15 That's too early. Let me get to the right 16 spot. 17 Here we go. 18 A. What paragraph? 19 Q. Paragraph 67, on page 18. Let me 20 know -- let me know when you're there? 21 A. Right. 22 Q. "In my opinion, once J&amp;J had 23 evidence of, A, the presence of asbestos 24 because of its non-carcinogenicity and absence 25 of a threshold dose or the presence of</p>	<p style="text-align: right;">Page 296</p> <p>1 biological activity of those fibers. 2 And they believe that elongate 3 particles, right, of a certain aspect 4 ratio of at least 3 to 1, right, should -- 5 should be assessed for their biological 6 activity. 7 That's what the working group has 8 said in all this focus on if this is 9 asbestiform, we're going to look at this 10 way. We're going to look it at that way. 11 We're going to define it this way. We're 12 going to make it so specific, right. It's 13 not sensitive enough. 14 This is the point when you're 15 dealing with these sets of minerals in 16 fibrous form, and we're talking about the 17 amphiboles; and we're talking about talc. 18 And that's what the working group is 19 doing. Their focus is on elongate 20 particles. That was my only point. 21 BY MR. EWALD: 22 Q. So but the question is -- you 23 talked about the SEM issues. Isn't the 24 question that's been raised in part B is: Are 25 they really seeing fibers?</p>
<p style="text-align: right;">Page 295</p> <p>1 non-asbestiform amphiboles or fibrous talc, the 2 safety of their product was not established." 3 My question to you is: Should we 4 also add fibrous chlorite to that? 5 A. No. 6 Q. Okay. So you're okay with fibrous 7 chlorite? 8 MS. O'DELL: Object to the form. 9 THE WITNESS: I'm sorry. 10 MS. O'DELL: What is -- you know, 11 John, what's your question? 12 What's the topic here? 13 MR. EWALD: The topic is -- is that 14 your witness is now saying that fibrous 15 chlorite has been identified by IWGACP as 16 something that's harmful, and he should 17 add it to the list, right? 18 THE WITNESS: No, sir. I mean, 19 again, I apologize if I wasn't clear. 20 The -- the -- what -- the working 21 group was very clear. They are getting 22 into these -- this definition of 23 non-asbestiform or asbestiform has 24 obfuscated in the context of the minerals 25 amphiboles as well as talc, right, the</p>	<p style="text-align: right;">Page 297</p> <p>1 Isn't that the question? 2 A. It's reliability of the SEM method, 3 right? 4 Q. Well, it goes on to say that on B, 5 "The Dutch Consumer Organization attempted to 6 determine the asbestos content by scanning 7 electron microscopy and X-ray energy dispersive 8 analysis." 9 A. Right. 10 Q. "By this combined technique, one 11 can look at the morphology of particles" -- and 12 it goes on to say, blah, blah, blah. And "One, 13 when preparing talc for scanning electron 14 microscopy (SEM) analysis, many talc platelets 15 lie perpendicular to the viewing plane and thus 16 from an edge-on-view look like a fiber." 17 A. Right. 18 Q. But they're not a fiber? 19 A. He's objecting to SEM, correct? 20 That's what Mr. Rolle is doing. 21 He's saying the SEM is not reliable here. 22 Q. I think what he's saying, Doctor, 23 is that if you don't know what you're looking 24 at, you could be calling a talc platelet lying 25 perpendicular as a fiber; isn't that what he's</p>

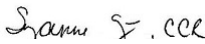


<p style="text-align: right;">Page 298</p> <p>1 saying there?</p> <p>2 MS. O'DELL: Object to the form.</p> <p>3 THE WITNESS: What he's saying is</p> <p>4 that SEM is not a reliable method to do</p> <p>5 that, fair?</p> <p>6 BY MR. EWALD:</p> <p>7 Q. And what -- I'm not agreeing with</p> <p>8 you one way or another.</p> <p>9 But what is your opinion on whether</p> <p>10 or not SEM is an appropriate analytical</p> <p>11 technique for the presence of talc?</p> <p>12 A. Well, I know when -- I know when</p> <p>13 Bill Ashton went to China and wanted to invest</p> <p>14 J&amp;J's money and shift that to Vermont to use</p> <p>15 SEM.</p> <p>16 Q. Okay. Do you understand that you</p> <p>17 can use the right instrument but not know how</p> <p>18 to use it to analyze the matrix appropriately?</p> <p>19 Do you understand that's a</p> <p>20 possibility?</p> <p>21 A. Exactly. And if you look at Rio</p> <p>22 Tinto's analysis and you look at the individual</p> <p>23 variability between laboratories, you just hit,</p> <p>24 right, another key element of why asbestos was</p> <p>25 being masked.</p>	<p style="text-align: right;">Page 300</p> <p>1 been referring to it. This is on historical</p> <p>2 development of the framework to the IMERYYS</p> <p>3 document on fiber management overview in 2011</p> <p>4 on transmission electron microscopy, and it</p> <p>5 says, "TEM has been used by Cyprus, Luzenac" --</p> <p>6 blah, blah -- "in IMERYYS personal care products</p> <p>7 since 1990s. TEM was incorporated to include</p> <p>8 all other types in 2001. TEM gained favor in</p> <p>9 the 1990s as a technique with the lowest</p> <p>10 limited detection, especially in the U.S." --</p> <p>11 blah, blah. "TEM is recognized as the best</p> <p>12 method for chrysotile detection due to the</p> <p>13 ultimate resolution crystal structure</p> <p>14 determination lowest limited detection."</p> <p>15 I just wanted to make sure that was</p> <p>16 the context of how TEM was looked at certainly</p> <p>17 by J&amp;J suppliers. I am not in any way</p> <p>18 questioning J&amp;J. The documents you set out in</p> <p>19 724, 719, they are what they are.</p> <p>20 But just certainly, the people who</p> <p>21 are producing this, basically, I mean, they</p> <p>22 believe from this that they incorporated TEM in</p> <p>23 the 1990s sort of routinely. That's my only</p> <p>24 point.</p> <p>25 Q. All right. So I'm going to --</p>
<p style="text-align: right;">Page 299</p> <p>1 Whenever Rio Tinto had as positive,</p> <p>2 they sent it to another lab. Okay. Not when</p> <p>3 it was negative, but when it was positive.</p> <p>4 They sent it to another lab, and they knew,</p> <p>5 right, the reliability of the other labs was</p> <p>6 great variability. You can look at their own</p> <p>7 assessments, right, and they did it for one</p> <p>8 reason. And they said it. They did it for</p> <p>9 liability reasons. They found a positive.</p> <p>10 They send it out, right.</p> <p>11 And what you see the history of</p> <p>12 retesting and retesting, right. When you had a</p> <p>13 positive, you retested it into a negative,</p> <p>14 right. That's how you get, along with all</p> <p>15 these other methods, that's how you say there's</p> <p>16 no asbestos here.</p> <p>17 (Discussion held off the record.)</p> <p>18 (Whereupon, a break was taken.)</p> <p>19 BY MR. EWALD:</p> <p>20 Q. Dr. Kessler, I understand you have</p> <p>21 something else you'd like to clarify.</p> <p>22 A. Yeah. I just want to clarify.</p> <p>23 You're very kind. I appreciate it.</p> <p>24 You should have in the chat --</p> <p>25 we've been referring to it several times. I've</p>	<p style="text-align: right;">Page 301</p> <p>1 MR. EWALD: Jake, can you put in</p> <p>2 17.04. That 01 one.</p> <p>3 BY MR. EWALD:</p> <p>4 Q. Doctor, let me know when you have a</p> <p>5 chance to take a look at it.</p> <p>6 A. Yep. Let me just get it. Thank</p> <p>7 you for putting it in.</p> <p>8 MS. O'DELL: Are you going to mark</p> <p>9 this as an exhibit, John?</p> <p>10 MR. EWALD: Yes. It will be, I</p> <p>11 think, Exhibit 18.</p> <p>12 MS. O'DELL: Okay.</p> <p>13 MR. EWALD: And for the record,</p> <p>14 it's -- hold on.</p> <p>15 THE COURT REPORTER: I think this</p> <p>16 should be 19.</p> <p>17 MR. EWALD: Oh, really. Sorry.</p> <p>18 It's Bates Number JNJ 000404835</p> <p>19 with the date of April 13th, 1994.</p> <p>20 Subject: Update on FDA/NTP.</p> <p>21 (Whereupon, Exhibit 19, Memorandum</p> <p>22 dated April 13, 1994, Bates labeled</p> <p>23 JNJ 000404835, was marked for</p> <p>24 identification.)</p> <p>25</p>

<p style="text-align: right;">Page 302</p> <p>1 BY MR. EWALD:</p> <p>2 Q. Do you have it in front of you,</p> <p>3 Doctor?</p> <p>4 A. I do.</p> <p>5 Q. And this is discussing from Steven</p> <p>6 Gettings to Talc Interested Party Task Force.</p> <p>7 "We have learned the driving force</p> <p>8 behind NTP's decision to analyze exposed</p> <p>9 animals/human tissues for the presence of talc</p> <p>10 is FDA.</p> <p>11 "The issue has been discussed at</p> <p>12 high level meetings at FDA between the</p> <p>13 Commissioner and representatives of consumer</p> <p>14 groups."</p> <p>15 Did I read that correctly?</p> <p>16 A. Exactly.</p> <p>17 Q. Does that ring any bells about</p> <p>18 meetings that you had with representatives of</p> <p>19 consumer groups about concerns about talc?</p> <p>20 A. I have no -- no. I see this here.</p> <p>21 It doesn't ring any bells whatsoever. I'm not</p> <p>22 saying it didn't happen. Just I have no</p> <p>23 recollection of this whatsoever. If you</p> <p>24 have -- you know, I just don't see it.</p> <p>25 Q. Fair enough.</p>	<p style="text-align: right;">Page 304</p> <p>1 do that.</p> <p>2 MR. O'DELL: Okay.</p> <p>3 THE WITNESS: Yeah. I have the</p> <p>4 document.</p> <p>5 BY MR. EWALD:</p> <p>6 Q. And this is from, again, Stephen</p> <p>7 Gettings, dated July 1st, 1994, to the Talc</p> <p>8 Interested Party Task Force, Meeting Summary</p> <p>9 (FDA/NTP). It talks about a June 28th, 1994,</p> <p>10 delegation from CTFA.</p> <p>11 "Met with representatives of FDA</p> <p>12 and NTP."</p> <p>13 Discussed various issues relating</p> <p>14 to talc. And if you scroll down to the first</p> <p>15 bullet on the second page, it reads, "FDA</p> <p>16 conceded that they are responding to pressure</p> <p>17 from within the Commissioner's Office</p> <p>18 (particularly from the Special Assistant to the</p> <p>19 Commissioner on Women's Issues and from the FDA</p> <p>20 Office of Public Affairs), to fully investigate</p> <p>21 any association between the talc and the</p> <p>22 etiology of ovarian cancer."</p> <p>23 Did I read that correctly?</p> <p>24 A. They are good. I mean, I'm proud</p> <p>25 of them. Now it makes sense. I think I</p>
<p style="text-align: right;">Page 303</p> <p>1 A. I don't recall, you know. I did</p> <p>2 it -- the issue is -- I mean, I always like --</p> <p>3 you -- it's amazing how people invoke, you</p> <p>4 know, commissioner meetings. I mean, this is</p> <p>5 a -- this is a J&amp;J -- internal J&amp;J meeting</p> <p>6 memo.</p> <p>7 Q. It's at the top, Talc Interested</p> <p>8 Party Task Force.</p> <p>9 A. I -- I have no idea. It could be</p> <p>10 correct. It could not be correct. I just</p> <p>11 don't know, sir. I have no recollection.</p> <p>12 Q. No worries.</p> <p>13 MR. EWALD: So, Jake, now throw in</p> <p>14 the 17.007.</p> <p>15 For the record, we'll mark this</p> <p>16 Exhibit 20, and it's Bates Number</p> <p>17 JNJ 000016687.</p> <p>18 (Whereupon, Exhibit 20, Memorandum</p> <p>19 dated July 1, 1994, Bates labeled</p> <p>20 JNJ 000016687 and JNJ 000016688, was</p> <p>21 marked for identification.)</p> <p>22 THE WITNESS: Hold on one second.</p> <p>23 MS. O'DELL: Do you have it</p> <p>24 downloaded?</p> <p>25 THE WITNESS: Yeah. I'm going to</p>	<p style="text-align: right;">Page 305</p> <p>1 figured -- go ahead. Keep on going.</p> <p>2 Q. Well, what's -- what's your</p> <p>3 revelation?</p> <p>4 A. Remember you said there were two</p> <p>5 FDA, besides Gilbertson, at the -- that</p> <p>6 workshop?</p> <p>7 Q. Yes.</p> <p>8 A. That symposium, you remember you</p> <p>9 mentioned Carol Schmenan?</p> <p>10 Q. Yes.</p> <p>11 A. Right. You remember I said Ruth</p> <p>12 Merkatz was there, right?</p> <p>13 Q. Yes.</p> <p>14 A. Dr. Ruth Merkatz. Those are</p> <p>15 highly, highly competent -- you know,</p> <p>16 Dr. Merkatz is one of the great women health</p> <p>17 professionals, worked at the FDA, worked at</p> <p>18 Pfizer, did -- worked for the Population</p> <p>19 Council, a leader in reproductive freedom for</p> <p>20 women. Carol Schmenan equally, you know.</p> <p>21 I'm glad while I'm doing other</p> <p>22 stuff, they were focused on this apparently.</p> <p>23 So I'm sure that's what -- that's what this</p> <p>24 says.</p> <p>25 So FDA conceded they were</p>

<p style="text-align: right;">Page 306</p> <p>1 responding to Ruth -- you know, Special 2 Assistant to Commissioner of Women's Health, 3 Dr. Ruth Merkatz, and from the Office of Public 4 Affairs is Carol Schmenan. They were the two 5 at the meeting, and they were -- yeah, they 6 were doing their jobs. 7 This is an important women's issue, 8 and they were apparently focused on it. 9 Q. Okay. And after fully 10 investigating any association between talc and 11 the etiology of ovarian cancer, there's no 12 action taken during your administration at the 13 FDA relating to that issue, correct? 14 MS. O'DELL: Object to the form. 15 THE WITNESS: You're telling the 16 FDA there's no asbestos in talc. I mean, 17 I don't -- I don't believe -- I can go 18 back -- I'm happy to ask Ms. Schmenan and 19 Dr. Merkatz whether they were aware in 20 1994, right, that there was asbestos in 21 talc of the -- of the evidentiary record. 22 I was not. I didn't -- you know, I 23 certainly didn't understand those issues. 24 So, you know, when you say 25 "investigating," I don't -- I mean,</p>	<p style="text-align: right;">Page 308</p> <p>1 THE WITNESS: Yeah. I'm sorry. 2 Now I just got kicked under the table. 3 BY MR. EWALD: 4 Q. If you wouldn't mind turning to 5 187, paragraph 187 of your report, page 87. 6 A. Sorry. 18- -- paragraph 187? 7 Q. Yes. 8 A. Thank you, sir. 9 Q. Sure. And it carries over to 10 page 88. And it's talking about Vernon Zeitz 11 and a handwritten letter about the Department 12 of Health Education and Welfare contacting him 13 about a government study of Vermont talc 14 workers. 15 My first question is: Have you 16 ever reviewed any materials relating to a 17 government study of Vermont talc workers? 18 A. I -- I have -- yes. 19 Q. Okay. 20 A. I mean, in my late nights and early 21 mornings in front of relativity, I found myself 22 maybe, you know, a while back, I mean, in some 23 of those documents; but it's a blur right now. 24 Q. All right. And so -- 25 A. This was -- was this -- this was an</p>
<p style="text-align: right;">Page 307</p> <p>1 maybe -- you know, I can't -- you'd have 2 to ask them whether they understood at 3 that time the evidence was what we see 4 now. 5 BY MR. EWALD: 6 Q. As you sit here today, you don't 7 know what they knew one way or another, right? 8 A. I can't tell you what was in -- but 9 it makes a lot of sense that Dr. Merkatz and 10 Ms. Schmenan were attending these meetings. 11 And if they were looking for certain studies to 12 be done, then the agency, you know, they were 13 doing their jobs. 14 Q. Okay. On -- 15 A. Do you have other -- do you have 16 other documents? I would love to see maybe to 17 clarify. 18 Q. You're the one that's coming off of 19 seven hours so... 20 I might have more to show you. 21 A. I'm happy to come to Brooklyn. 22 Q. Just look at, if you wouldn't 23 mind -- 24 MS. O'DELL: That was an 25 unauthorized statement.</p>	<p style="text-align: right;">Page 309</p> <p>1 NIH study if I'm correct. 2 Q. And so the -- you have a quote here 3 from Vernon Zeitz in, say, the late '70s. And 4 it talks about, amongst other things, your 5 legions, "If we are to be those legions, it is 6 imperative we overcome the inertia of our past 7 to modernize and mobilize our defenses and 8 offenses so we enter into battle with the 9 outcome assured," right? 10 A. That's what it says. 11 Q. Right. And when you take that 12 letter and, say, in paragraph 188, "In my 13 opinion, J&amp;J decided in 1970s to aggressively 14 defend its product. That strategy kept their 15 product in the market for 50 years but put the 16 public's health at risk. It may not have been 17 that way if J&amp;J was willing to bear any 18 additional cost in reformulating the product." 19 That's what you write, right? 20 A. That's what I write. 21 Q. And are you suggesting in a Vernon 22 Zeitz's letter in the late 1970s was 23 internalized and held forth in the company over 24 the ensuing 50 years? 25 MS. O'DELL: Object to the form.</p>

<p style="text-align: right;">Page 310</p> <p>1 THE WITNESS: No. I -- I am not,  2 but I do have the impression that -- no,  3 I'm not -- I'm not implicating Mr. Zeitz.  4 I'm responsible for my -- my opinion  5 there. I mean, this is the totality of  6 the picture that I see.  7 BY MR. EWALD:  8 Q. Okay. And you say that they put  9 the public health at risk because they weren't  10 willing to bear any additional costs to  11 reformulate the product.  12 That's what you write, right?  13 A. Yeah. I think "additional" may not  14 be the most artful word. I mean, there was --  15 they didn't -- they didn't go -- you know, they  16 obviously didn't go to corn starch. There was  17 a price differential there. That's all I mean.  18 Q. Okay. And so is it the opinion  19 that you're offering to a reasonable degree of  20 certainty that J&amp;J knew its product contained  21 asbestos, knew that it put the public at risk,  22 but just decided to sell it anyway; that's your  23 view?  24 A. No. I'm -- I am -- you're using  25 the word "knew," okay. I'm not going to use</p>	<p style="text-align: right;">Page 312</p> <p>1 think every aspect of that sentence is -- you  2 know, I don't know how you -- tell me what you  3 dispute in that sentence or sentences.  4 Q. Well, again, I know it's been a  5 long day, but I still don't have to answer your  6 questions.  7 My question to you, then, is:  8 Throughout the day you've returned to this idea  9 that J&amp;J intentionally used test methods to  10 mask the presence of asbestos.  11 How is there any way to understand  12 that conclusion other than that J&amp;J knowingly  13 put baby powder and other talc products on the  14 market that has asbestos in it?  15 MS. O'DELL: Object to the form.  16 THE WITNESS: So I -- there's  17 nothing I'm the talking about intent here.  18 Okay.  19 What I think -- and I'm very  20 serious about this. You may not  21 understand that for anyone listening on  22 this phone, right.  23 I think if you look at the  24 evidence, okay, and you just look  25 objectively at the evidence -- and I don't</p>
<p style="text-align: right;">Page 311</p> <p>1 the word -- I don't use the word "knew" there.  2 Okay. Let's take --  3 Q. I'm not --  4 A. Let's take it out of the subjective  5 intent. It depends how you use the word  6 "knew." J&amp;J knew. J&amp;J decided.  7 I mean, there was -- I don't think  8 there's any question -- you tell me if I'm  9 wrong -- aggressively defended its product,  10 right. I mean, that has been the strategy for  11 50 years, right.  12 That strategy kept the -- their --  13 their product on the market for 50 years.  14 There's a strategy to switch to corn starch.  15 That strategy put the public health at risk. I  16 don't think there's any question about that.  17 You look at the epidemiological  18 studies. There is a small statistically  19 significant public health need.  20 It may not be that way. It didn't  21 have to be that way. J&amp;J could have gone to  22 corn starch and reformulated its product.  23 I don't see how you can disagree  24 with anything in that statement. It has  25 nothing to do with Johnson &amp; Johnson knew. I</p>	<p style="text-align: right;">Page 313</p> <p>1 think people are focused on this -- I  2 mean, and again, I'm still learning,  3 right. I mean, and there's still -- you  4 know, there's still much to understand,  5 right.  6 But at every stage, just processing  7 it is going to mask it. The way it was  8 tested, we spent -- you didn't ask me  9 anything about putting it through a 325  10 mesh, right. 325 mesh you're going to  11 diminish the pickup, right. I mean, at  12 every stage here, right, you decrease the  13 chances of picking up asbestos, right.  14 What people intended, that's not my  15 job. Okay. But a reasonable -- let me  16 just finish.  17 A reasonable and sophisticated  18 company, right, when you look at the  19 grinding and the crushing and the milling,  20 when you look at the passing it through  21 these sieves, you look at the sensitivity,  22 you look at the five-counting rule, you  23 look at the retesting, you know, it -- you  24 see -- certainly J&amp;J documents say, you  25 know, TEM, too sensitive. Can't use it.</p>

<p style="text-align: right;">Page 314</p> <p>1 Okay. Put it all together, one way 2 or another, detection of asbestos -- I am 3 100 percent confident -- was masked, 4 right. I mean, in this by a whole series 5 of steps. 6 When Ashton knew -- what Bill 7 Ashton knew, what he did, we're not going 8 to know, right. 9 But when you look at this, right, 10 there's no doubt that the manufacturing 11 process, right, and the testing and, you 12 know, the mask the presence of asbestos. 13 And that's -- I mean, that's -- that to me 14 is key here. 15 You keep on saying there's no 16 asbestos. There's never been asbestos. 17 There -- it makes no sense. You put in 18 place a method to detect it, and you never 19 detected it. So what good was the method 20 of detecting it. That was the fatal flaw, 21 right. 22 And you -- the last document you 23 talked about NTP, right. J&amp;J's -- I mean, 24 the staff there wanted NTP not to classify 25 this as a carcinogen. They said there was</p>	<p style="text-align: right;">Page 316</p> <p>1 for all the reasons we discussed today. 2 MR. EWALD: Okay. Doctor, I think 3 my time's up. Thanks. 4 THE WITNESS: Thank you, sir. 5 MS. O'DELL: I have no questions. 6 MR. EWALD: Thank you. 7 THE COURT REPORTER: Counsel, 8 before everybody leaves, regular delivery 9 on the transcript? 10 Mr. Ewald, regular delivery on the 11 transcript? 12 MR. EWALD: Yes. 13 (The witness is excused.) 14 (Deposition of David A. Kessler, 15 M.D., concluded at 7:15 p.m. EDT.) 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 315</p> <p>1 a fatal flaw, right, and that's actually 2 one of the things that got me thinking 3 about this. 4 What was the fatal flaw to get NTP 5 not to classify it? And the 6 classification -- the fatal flaw that J&amp;J 7 employees came up with to get NTP was -- 8 you know, you can -- your epi is not right 9 because before 1976 there was asbestos in 10 there, right. And after 1976, we cleaned 11 it up; and there was no asbestos. 12 That was the fatal flaw NTP; and 13 therefore, you can't rely on the -- you 14 can't rely on it to classify it as a 15 possible carcinogen. 16 The fatal flaw here, as you put it, 17 was the industry in J&amp;J putting J4-1, 18 screen out the asbestos and it never had a 19 positive. That's the fatal flaw in the 20 whole argument, right. That can't be, and 21 I don't understand that. 22 The only way to -- the answer to 23 that question, right, is that when you 24 look, the reason why you were able to say 25 no asbestos, no asbestos, no asbestos is</p>	<p style="text-align: right;">Page 317</p> <p>1 C E R T I F I C A T E 2 3 4 I, SUZANNE J. STOTZ, a Certified 5 Court Reporter, Registered Professional 6 Reporter, Certified Realtime Reporter, and 7 Notary Public in and for the State of New 8 Jersey, do hereby certify that the foregoing is 9 a true and accurate transcript of the 10 stenographic above-captioned matter. 11 12  13 14 SUZANNE J. STOTZ, CCR, RPR, CRR 15 LICENSE NO. 30XI00184500 16 17 18 DATED: April 25, 2024 19 20 21 NOTE: THE CERTIFICATE APPENDED TO THIS 22 TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION 23 OF THE SAME BY ANY MEANS, UNLESS UNDER THE 24 DIRECT CONTROL AND/OR DIRECTION OF THE 25 CERTIFYING COURT REPORTER.</p>



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## 1           E R R A T A   S H E E T

2       I have read my testimony in the foregoing  
3 transcript and believe it to be true and  
4 correct to the best of my knowledge and belief  
5 with the following changes:

6   PAGE    LINE       CHANGE

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19   WITNESS SIGNATURE           DATE

20   \_\_\_\_\_

21   Sworn and subscribed to before me this

22   \_\_\_\_\_ day of \_\_\_\_\_, 2024.

23   \_\_\_\_\_

24   Notary Public of the

25   State of \_\_\_\_\_.

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[comfortable - conclusion]

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[we've - word]

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[word - yeah]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted

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